UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF OHIO
WESTERN DIVISION

UNITED STATES OF AMERICA, *ex rel.*

MARC YOUNG
25963 Stone Canyon
San Antonio, TX 78260;

JEREMY W. BRIGGS
7219 Washita Way
San Antonio, TX 78256; and

JOSEPH B. LAWRENCE
630 Sentry Hill
San Antonio, TX 78260

BRINGING THIS ACTION ON BEHALF OF THE UNITED STATES OF AMERICA

c/o Hon. Benjamin C. Glassman
United States Attorney
221 E. 4th Street, Suite 400
Cincinnati, OH 45202; and,

Hon. Jefferson B. Sessions
Attorney General of the United States
Department of Justice
950 Pennsylvania Avenue, NW
Washington, DC 20530-0001

Plaintiffs and Relators,

v.

AvKARE, INC.
615 N 1st Street
Pulaski, TN 38478

Agent: Troy A. Mizell
615 N. 1st Street
Pulaski, TN 38478

Defendant.

Civil Action No. 1:17-cv-421

UNITED STATES DISTRICT JUDGE SUSAN J. DLOTT

FIRST AMENDED COMPLAINT

Filed under seal pursuant to 31 U.S.C. § 3730(b)(2)

DO NOT SERVE

DO NOT PUT ON PACER

Relators bring this action on behalf of the United States and on their own behalf and allege the following:

I. INTRODUCTION

1. This is a *qui tam* action brought by Relators Marc Young, Jeremy W. Briggs, and Joseph B. Lawrence **("Relators**") on behalf of the United States against Defendant AvKARE, Inc. ("**Defendant AvKARE**" or "**AvKARE**") to recover damages and civil penalties arising from false or fraudulent statements, records, and claims made, used, or caused to be made or used by Defendant AvKARE in violation of the False Claims Act, 31 U.S.C. § 3729, *et seq*.

2. Defendant AvKARE is a re-labeler of generic pharmaceutical products. AvKARE is located in Pulaski, Tennessee.

3. Defendant AvKARE falsely represented and/or certified the country of origin for pharmaceutical products as being from Trade Agreements Act ("**TAA**") designated countries in order to obtain United States Government contracts, and knowingly sold or caused the sale of non-TAA compliant pharmaceutical products to the United States in violation of the express terms of those Government contracts. The Government contracts at issue include Contract No. VA797P-14-C-0021 (**ranitidine**); Contract No. SPE2D2-15-D-0015 (**metformin HCL ER**); Contract No. VA797P-15-C-0013 (**lamotrigine IR**); Contract No. SPE2D2-15-D-0022 (**ibuprofen**); Contract No. SPE2D2-16-D-0040 (**metaxalone)**; Contract No. SPE2D2-16-D-0041 (**trazodone HCL**); Contract No. VA797P-13-C-0016 (**naproxen**); Contract No. VA797P-15-C-0049 (**fludrocortisone acetate**); Contract No. VA797P-16-C-0044 (**oxybutynin CL**); Contract No. VA797P-16-C-0060 (**venlafaxine HCL**); Contract No. VA797P-16-C-0068 (**montelukast SOD**); Contract No. VA797P-16-C-0074 (**diltiazem**); and Contract No. VA797P-16-C-0077

(**benazepril HCL**) (collectively referred to as "**the Government Contracts**").

4. Defendant AvKARE has been perpetrating this fraud scheme since at least December 27, 2012, and continuing to the present.

5. Defendant AvKARE carried out this fraudulent scheme across the United States by bidding on and accepting orders on national government contracts for the delivery of pharmaceutical products to pharmaceutical prime vendors for distribution to various governmental participants located throughout the United States, including medical treatment facilities, formularies, and eligible Government beneficiaries.

6. Defendant AvKARE's unlawful acts in violation of the False Claim Act, as alleged herein, arise from submitting and/or causing the submission of false claims for payment to the Federal Government for pharmaceutical products and AvKARE's use of materially false records and statements in support of those false claims. Defendant AvKARE falsely certified and/or represented that its pharmaceutical products were from TAA-designated countries, failed to truthfully certify that its pharmaceutical products were from non-TAA designated countries, sold the Federal Government pharmaceutical products that were not TAA-compliant and were ineligible for payment, and knowingly submitted or caused to be submitted fraudulent information to the Federal Government concerning the country of origin of its pharmaceutical products for the purpose of unlawfully obtaining contracts and payments that it was not entitled to receive.

II. PARTIES

7. Plaintiff in this action is the United States of America, on whose behalf Relators bring their claims.

8. Relator Marc Young is a pharmacist with extensive project management and clinical pharmaceutical expertise. Relator Young has a Doctor of Pharmacy degree (PharmD) from Idaho State University and a Master's in Pharmacy Care Systems from Auburn University.

9. Relator Jeremy W. Briggs is a pharmacist with more than 15 years of experience in the pharmaceutical industry. Relator Briggs has a Doctor of Pharmacy degree (PharmD) from the University of Kansas and an MBA from the University of Texas, San Antonio.

10. Relator Joseph B. Lawrence is a pharmacist with more than 20 years of experience in the pharmaceutical industry. Relator Lawrence has a BS in Pharmacy from Southwestern Oklahoma State University, an MBA from the University of Phoenix, and a Doctor of Pharmacy degree (PharmD) from the University of Florida, College of Pharmacy.

11. Defendant AvKARE is a Tennessee corporation located in Pulaski, Tennessee. AvKARE focuses on the sale of generic pharmaceuticals, including to various Federal Government entities. While AvKARE distributes the drugs and holds the contracts with the Government, it does not manufacture the drugs, instead it is simply the "Labeler" of the drugs at issue in this Complaint. Various other pharmaceutical companies are the "Manufacturers" of the drugs at issue.[1]

III. JURISDICTION AND VENUE

12. This action arises under the False Claims Act, 31 U.S.C. §§ 3729-3733. Relators

[1] Ranitidine, metformin HCL ER, ibuprofen, metaxalone, naproxen, and venlafaxine HCL are manufactured by Amneal Pharmaceuticals in New York. Lamotrigine IR is manufactured by Jubilant Cadista in Maryland. Trazodone HCL is manufactured by Teva Pharmaceuticals in Croatia. Diltiazem is manufactured by Anchen Pharmaceuticals in California. Relators have not been able to identify the manufacturers of fludrocortisone acetate, oxybutynin CL, montelukast SOD, and benazepril HCL.

bring this action pursuant to 31 U.S.C. § 3730(b)(1).

13. This Court has jurisdiction of the subject matter of this action pursuant to 28 U.S.C. §§ 1331 and 1345.

14. This Court has personal jurisdiction over Defendant AvKARE because AvKARE is a United States corporation conducting business in the United States and, pursuant to 31 U.S.C. § 3732(a), because AvKARE transacts business and committed acts proscribed by 31 U.S.C. § 3729 within this judicial district.

15. Venue is likewise proper in this judicial district under 31 U.S.C. § 3732(a) because Defendant AvKARE transacts business and committed acts proscribed by 31 U.S.C. § 3729 in this judicial district and in this division.

16. Personal jurisdiction and venue are proper in this district (and for venue in this division) specifically because, in violation of the express terms of its Government contracts, Defendant AvKARE caused the distribution of and sought reimbursement for non-TAA compliant pharmaceutical products distributed to the following Government entities located within this district and this division: the VA Medical Center located at 3200 Vine Street, Cincinnati, Ohio 45220; the VA Medical Center Dayton located at 4100 West Third Street, Dayton, Ohio 45428; the VA Medical Center located at 4337 Union Road, Middletown, Ohio 45005, and the VA Outpatient Clinic located at 512 South Burnett Road, Springfield, Ohio 45505. Defendant AvKARE also transacted business and committed acts proscribed by 31 U.S.C. § 3729 in this district: 1) by submitting claims for payment to the United States and receiving payment from the United States through Government pharmaceutical prime vendor Cardinal Health, Inc., which is located in this district in Dublin, Ohio; and 2) by distributing

drugs pursuant to its Government contracts through Government pharmaceutical prime vendors including Amerisource Bergen Drug Co. which maintains a distribution center in this district in Lockbourne, Ohio.

IV. THE FALSE CLAIMS ACT

17. The False Claims Act ("**FCA**") imposes liability upon any person who "knowingly presents, or causes to be presented, a false or fraudulent claim for payment or approval. . ." 31 U.S.C. § 3729(a)(1)(A).

18. The FCA also imposes liability upon any person who "knowingly makes, uses, or causes to be made or used, a false record or statement material to a false or fraudulent claim. . ." 31 U.S.C. § 3729(a)(1)(B).

19. The FCA defines "knowingly" to "mean that a person, with respect to information-(i) has actual knowledge of the information; (ii) acts in deliberate ignorance of the truth or falsity of the information; or (iii) acts in reckless disregard of the truth or falsity of the information." 31 U.S.C. § 3729(b)(1)(A). Proof of specific intent to defraud is not required. 31 U.S.C. § 3729(b)(1)(B).

20. Under the FCA, the term "claim"

> (A) means any request or demand, whether under a contract or otherwise, for money or property and whether or not the United States has title to the money or property, that—
> (i) is presented to an officer, employee, or agent of the United States; or
> (ii) is made to a contractor, grantee, or other recipient, if the money or property is to be spent or used on the Government's behalf or to advance a Government program or interest, and if the United States Government —
> (I) provides or has provided any portion of the money or property requested or demanded; or
> (II) will reimburse such contractor, grantee, or other recipient for any portion of the money or property which is requested or

demanded; and

(B) does not include requests or demands for money or property that the Government has paid to an individual as compensation for Federal employment or as an income subsidy with no restrictions on that individual's use of the money or property.

31 U.S.C. § 3729(b)(2).

21. Prior to filing this FCA action, Relators served upon the United States a copy of their Complaint and a written disclosure of substantially all material evidence and information they possessed, in accord with 31 U.S.C. § 3730(b)(2). Prior to filing this First Amended Complaint, Relators served upon the United States copy of this First Amended Complaint and a supplemental written disclosure of substantially all material evidence and information they possessed.

22. There has been no prior "public[] disclos[ure]," as that term is used in 31 U.S.C. § 3730(e)(4)(A), of the allegations and transactions on which this FCA action is based.

23. Relators are "original source[s]" of the information upon which the allegations and transactions in this complaint are based, in accord with 31 U.S.C. § 3730(e)(4)(B).

V. DEFENDANT AVKARE'S GOVERNMENT CONTRACTS REQUIRE COMPLIANCE WITH THE TRADE AGREEMENTS ACT

24. Pursuant to its Government contracts, Defendant AvKARE is required to certify that its pharmaceutical products that are end products of a Trade Agreements Act designated country.

25. In violation of the express terms of AvKARE's Government contracts, Defendant AvKARE knowingly sold or caused the sale of pharmaceutical products from non-TAA designated countries to the United States.

A. Trade Agreements Act Requirements

26. The Trade Agreements Act ("**TAA**"), 19 U.S.C. § 2501, *et seq*., requires that certain products procured by the United States Government must have specific designated countries as their country of origin.[2]

27. The TAA was enacted, in part, "to foster the growth and maintenance of an open world trading system" and "to expand opportunities for the commerce of the United States in international trade . . . ."[3]

28. The TAA applies to Government procurement contracts that equal or exceed certain threshold amounts. *See*, *e.g.*, 48 C.F.R. § 25.1101(c)(1); 48 C.F.R. § 225.1101(6); 78 Fed. Reg. 76700 (Dec. 18, 2013).[4]

29. Only specified countries qualify as TAA-designated countries of origin for products acquired by the United States Government.[5]

30. India, China, Brazil, and Russia are among the non-permitted countries of origin under the TAA.[6]

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[2] *See* 19 U.S.C. § 2512(a)(1)(A) (the President shall prohibit the procurement of products from non-designated foreign countries); *see also* 48 C.F.R. § 25.403(c)(1) (Under the TAA, the United States is to acquire only U.S.-made or designated country end products, for acquisitions covered by the World Trade Organization Government Procurement Agreement); 48 C.F.R. § 225.403(c) (same).

[3] 19 U.S.C. § 2502.

[4] For example, for calendar years 2012 and 2013, the TAA threshold amount for applicability was $202,000.00. 76 Fed. Reg. 76808, 76809 (Dec. 8, 2011). For calendar years 2014 and 2015, the TAA threshold amount for applicability was $204,000.00. 78 Fed. Reg. 76700 (Dec. 18, 2013). For calendar years 2016 and 2017, the TAA threshold amount for applicability is $191,000.00. 80 Fed. Reg. 77,694, 77695 (Dec. 15, 2015).

[5] *See* 48 C.F.R. § 52.225-5; 48 C.F.R. § 252.225-7021.

[6] *See, e.g.*, 48 C.F.R. § 52.225-5.

31. U.S. Government contracts over the specified threshold amounts include clauses that restrict the country of origin for items purchased by the U.S. Government.[7]

32. For an end product that consists of materials from more than one country, that end product's country of origin is the place where the materials have been "substantially transformed into a new and different article of commerce with a name, character, or use distinct from that of the article or articles from which it was so transformed." 19 U.S.C. § 2518(4)(B); 19 C.F.R. § 177.22(a).

33. The country of origin for a pharmaceutical product is the country in which the drugs's active pharmaceutical ingredient ("**API**") was sourced or produced.

34. Defendant AvKARE knows, as that term is defined in the FCA, that the country of origin for the following pharmaceutical products it sold to the Government (pursuant to contracts requiring TAA-compliant end products) were not TAA-designated countries:

a. ranitidine;

b. metformin HCL ER;

c. lamotrigine IR;

d. ibuprofen;

e. metaxalone;

f. trazodone HCL;

g. naproxen

h. fludrocortisone acetate;

i. oxybutynin CL;

[7] *See e.g.*, 48 C.F.R. § 25.1101(c)(1) & (c)(2).

j. venlafaxine HCL;

k. montelukast SOD;

l. diltiazem; and

m. benazepril HCL

35. As described more fully below, Defendant AvKARE is knowingly selling non-TAA compliant pharmaceutical products to the United States in violation of the False Claims Act.

B. The Pharmaceutical Prime Vendor Program

36. The Pharmaceutical Prime Vendor Program ("**PPV Program**") is the contracting method used by the United States Government to distribute drugs and other pharmaceutical products to the nation's veterans and to certain other Federal Government agencies.

37. Through the PPV Program, the Department of Veterans Affairs ("**VA**") provides pharmaceutical products to various VA facilities, to the Indian Health Service ("**IHS**"), to the Bureau of Prisons ("**BoP**"), and to other governmental entities. Authorized State Veterans Homes that have sharing agreements with VA facilities are also eligible participants in the PPV Program.

38. The Defense Logistics Agency ("**DLA**") likewise provides pharmaceutical products to the Department of Defense ("**DoD**") and to other governmental entities through the PPV Program.

39. Under the PPV Program, pharmaceutical distributors, including Defendant AvKARE, enter into contracts with the VA and the DLA. These Government contracts establish a national contract price for specific pharmaceutical products to be distributed through the PPV Program.

40. Pursuant to these VA and DLA contracts, the contractor agrees to allow the designated VA and DLA/DoD Pharmaceutical Prime Vendors to deliver the specified pharmaceutical products to various governmental entities.

41. A Pharmaceutical Prime Vendor ("**PPV**") is an independent business entity that functions as the primary distributor of specified classes of products such as drugs and pharmaceuticals for purchasers like VA hospitals and DoD medical facilities.

42. Contractors, including Defendant AvKARE, are required to provide the pharmaceutical products specified in the contract schedule at the prices established in the contract to designated PPVs for distribution to DoD, VA, BoP, and IHS facilities and to other governmental entities.

43. The PPVs place orders with the contractor for delivery to the PPVs who, in turn, distribute the pharmaceutical products to various governmental participants.

44. Under the terms of a Government contract with the VA or DLA, pharmaceutical providers, including Defendant AvKARE, agree to accept orders from PPVs and provide pharmaceutical products to the PPVs at the prices agreed to in the Government contract for use by the medical treatment facilities, formularies, and eligible beneficiaries served by those PPVs.

45. Pharmaceutical providers, including Defendant AvKARE, are required to report the dollar value of all sales made under a VA or DLA contract by calendar quarter. These reported sales must include all sales made, whether shipped directly to the users or through PPVs.

46. Under the terms of a VA or DLA contract, pharmaceutical providers, including Defendant AvKARE, are paid for the pharmaceutical products they deliver to PPVs by those

PPVs using Government funds.

47. Defendant AvKARE knowingly sold non-TAA compliant pharmaceutical products to the United States through the PPV program in violation of the False Claims Act.

48. TAA compliance is material to the Government. The Government regularly rejects bids for national contracts to supply pharmaceutical products when the TAA-compliance provision is not satisfied.

VI. AVKARE IS KNOWINGLY VIOLATING ITS GOVERNMENT CONTRACTS BY SUPPLYING NON-TAA COMPLIANT PHARMACEUTICAL PRODUCTS

49. As is described below in detail, the Government Contracts at issue in this Complaint required AvKARE to supply the Government with TAA-compliant pharmaceutical products.

50. Defendant AvKARE falsely certified its compliance with the Trade Agreements requirements of its Government contracts, including on the following occasions: January 12, 2015; December 17, 2015; February 17, 2016; and February 9, 2017.

51. Because AvKARE knowingly failed to supply TAA-compliant pharmaceutical products and because AvKARE falsely certified and/or represented its compliance with the Trade Agreements provisions in its Government contracts, the claims for payment under the contracts identified below are false claims.

A. The Ranitidine Contract: VA Contract No. VA797P-14-C-0021

52. On June 26, 2014, the VA issued Solicitation No. VA797P-14-R-0013 seeking offers to supply its requirements of ranitidine tablets.

53. Ranitidine is a generic version of the brand name drugs Taladine and Zantac. It is

used to treat and prevent ulcers, to treat conditions in which the stomach produces too much acid, and to treat gastroesophageal reflux disease (GERD) and other conditions in which acid backs up from the stomach into the esophagus.

54. By making an offer on Solicitation No. VA797P-14-R-0013, Defendant AvKARE agreed to furnish and deliver ranitidine tablets subject to the terms and conditions specified in the solicitation.

55. On August 22, 2014, Defendant AvKARE was awarded Contract No. VA797P-14-C-0021 to supply ranitidine tablets to the VA pursuant to Solicitation No. VA797P-14-R-0013 (collectively the "**Ranitidine Contract**").

56. The Ranitidine Contract is a firm fixed price requirements contract whereby Defendant AvKARE agreed to supply ranitidine tablets for distribution to VA, DoD, IHS, and BoP facilities, as well as to Federal Health Care Centers and to specified State Veteran Homes.

57. The Ranitidine Contract is for one base year, with four one-year option years.

58. The Ranitidine Contract has a contract award amount of $27,043,130.95. This award amount is an estimate of the total value of all annual orders by the various Government facilities for this drug.

59. The effective date of the base year of the Ranitidine Contract was August 27, 2014.

60. On July 21, 2015, the VA exercised the first one year option available under the Ranitidine Contract, permitting governmental entities to place orders under that contract during the one year time period beginning on August 27, 2015.

61. On July 27, 2016, the VA exercised the second option year available under the

Ranitidine Contract, permitting governmental entities to place orders under that contract from August 27, 2016 through August 26, 2017.

62. The products awarded under the Ranitidine Contract are ordered and distributed through the PPV Program.

63. The Ranitidine Contract specifies that PPVs will accept Government orders of ranitidine and payment for such orders on behalf of Defendant AvKARE.

64. The Ranitidine Contract identifies one VA PPV and five DoD PPVs. Cardinal Health of Dublin, Ohio is one of the designated DoD PPVs.

65. The governmental facilities served under the Ranitidine Contract include the VA Medical Center located at 3200 Vine Street, Cincinnati, Ohio 45220; the VA Medical Center Dayton located at 4100 West Third Street, Dayton, Ohio 45428; the VA Medical Center located at 4337 Union Road, Middletown, Ohio 45005, and the VA Outpatient Clinic located at 512 South Burnett Road, Springfield, Ohio 45505.

66. The Ranitidine Contract provides that all delivery orders under that contract "are subject to the terms and conditions of this contract."

67. The Ranitidine Contract states that, "A contract will be awarded to the responsible offeror that submits an offer meeting the solicitation requirements, and is the lowest price technically acceptable offer."

68. The Ranitidine Contract provides that the Government may terminate the contract for cause if Defendant AvKARE fails to comply with any contract terms and conditions. In the event of such a termination for cause, Defendant AvKARE shall be liable to the Government for any and all rights and remedies provided by law.

69. The Ranitidine Contract specifically requires Defendant AvKARE to comply with FAR provision 52.225-5, Trade Agreements (Nov 2013) (19 U.S.C. § 2501, *et seq*., 19 U.S.C. § 3301 note).

70. The Ranitidine Contract also specifically requires Defendant AvKARE to certify that "each end product . . . is a U.S.-made or designated country end product, as defined in the clause of this solicitation entitled 'Trade Agreements'" and to list non-compliant end products. This provision of the Ranitidine Contract also expressly states that, "The Government will consider for award only offers of U.S.-made or designated country end products unless the Contracting Officer determines that there are no offers for such products or that the offers for such products are insufficient to fulfill the requirements of the solicitation."[8]

71. Defendant AvKARE is required to certify Trade Agreements compliance on an annual basis.

72. On January 12, 2015, Julie Roberts attested to the accuracy of AvKARE's Trade Agreements compliance and made these annual certifications; thereafter on December 17, 2015, February 17, 2016, and February 9, 2017, David Dunston attested to the accuracy of AvKARE's Trade Agreements compliance and made these annual certifications.

73. Specifically, on January 12, 2015, Julie Roberts executed the Trade Agreements certification for AvKARE for the time period of January 12, 2015 through January 12, 2016, certifying on behalf of AvKARE that each end product (except those listed) is a U.S.-made or designated country end product. (No non-compliant end products were listed).

74. On December 17, 2015, February 17, 2016, and February 9, 2017, David Dunston

[8] No such determinations were made by the Contracting Officer.

executed this same Trade Agreements Certificate for Defendant AvKARE for the respective one year period beginning on each of those dates.

75. By submission of its offer for the Ranitidine Contract and in its annual certifications, AvKARE verified that its Trade Agreements certification was current, accurate, complete, applicable to this solicitation, and incorporated by reference.

76. However, the ranitidine tablets Defendant AvKARE provides to governmental entities under Contract No. VA797P-14-C-0021 are not U.S.-made or designated country end products as defined in FAR provision 52.225-5, Trade Agreements (Nov 2013).

77. The ranitidine tablets supplied by Defendant AvKARE under the Ranitidine Contract are end products of a non-TAA designated country of origin.

78. In order to obtain the Ranitidine Contract, additional option years under that contract, and payments pursuant to that contract, Defendant AvKARE falsely certified that the ranitidine it was selling was a "U.S.-made or designated country end product."

79. Because the ranitidine tablets distributed by Defendant AvKARE are not a product of a TAA-designated country of origin, they are ineligible for Government procurement under the express terms of Contract No. VA797P-14-C-0021.

80. Defendant AvKARE falsely represented that the ranitidine it supplied under Contract No. VA797P-14-C-0021 was a TAA-compliant product.

81. Defendant AvKARE's certifications that the ranitidine tablets supplied under Contract No. VA797P-14-C-0021 were made in the United States or in a TAA "designated country" were false. AvKARE made these false certifications "knowingly," as that term is defined 31 U.S.C § 3729(b)(1).

82. As specified in the Ranitidine Contract and reiterated in the Trade Agreements Certificate, the Government would not have awarded the Ranitidine Contract, or option years under that contract, to Defendant AvKARE and AvKARE would not have been paid any money for ranitidine tablets if AvKARE had truthfully disclosed in its bid that the country of origin for the ranitidine tablets was a non-TAA country of origin.

83. All claims for payment for ranitidine tablets supplied by Defendant AvKARE under Contract No. VA797P-14-C-0021 are false claims.

B. The Metformin HCL ER Contract: DLA Contract No. SPE2D2-15-D-0015

84. On July 3, 2014, the DLA issued Solicitation No. SPE2D2-14-R-0002 seeking offers to supply its requirements of metformin HCL ER tablets.

85. Metformin HCL ER is a generic version of the brand name drugs Fortamet, Glucophage, Glumetza, and Riomet. It is an oral diabetes medicine that helps control blood sugar levels in patients with type 2 diabetes.

86. By making an offer on Solicitation No. SPE2D2-14-R-0002, Defendant AvKARE agreed to furnish and deliver metformin HCL ER tablets subject to the terms and conditions specified in the solicitation.

87. On October 16, 2014, Defendant AvKARE was awarded Contract No. SPE2D2-15-D-0015 to supply metformin HCL ER tablets to the DLA pursuant to Solicitation No. SPE2D2-14-R-0002 (collectively the "**Metformin HCL ER Contract**").

88. The Metformin HCL ER Contract is a firm fixed price requirements contract whereby Defendant AvKARE agreed to supply metformin HCL ER tablets for distribution to Federal Government entities including the VA, DoD, IHS, and BoP.

89. The Metformin HCL ER Contract is for one base year, with four one-year option years.

90. The Metformin HCL ER Contract has a contract award amount of $19,775,587.75. This award amount is an estimate of the total value of all annual orders by the various government facilities for this drug.

91. The effective date of the base year of the Metformin HCL ER Contract was October 16, 2014.

92. On October 14, 2015, the DLA exercised the first one year option available under the Metformin HCL ER Contract, permitting governmental entities to continue placing orders under that contract from October 16, 2015 through October 15, 2016.

93. On October 14, 2016, the DLA exercised the second year option available under the Metformin HCL ER Contract, permitting governmental entities to continue placing orders under that contract from October 16, 2016 through October 15, 2017.

94. The Metformin HCL ER Contract specifies that Defendant AvKARE, as the awarded contractor, consents to allow VA and DoD PPVs to distribute the listed products at the prices established in that contract.

95. The Metformin HCL ER Contract requires Defendant AvKARE to provide the products specified in the schedule at the prices established to all eligible DoD, VA, BoP and IHS customers.

96. The Metformin HCL ER Contract establishes a national supply source, in accordance with FAR 52.216-21 Requirements, to provide the drugs listed in the schedule for purchase by DLA and VA customers through the PPV.

97. The Metformin HCL ER Contract requires Defendant AvKARE to accept orders from designated PPVs at the prices agreed to under the contract and to deliver metformin HCL ER tablets to PPVs for distribution to DoD and VA medical treatment facilities, formularies, and eligible Government beneficiaries.

98. The Metformin HCL ER Contract requires Defendant AvKARE to establish a business relationship with the PPVs.

99. The Metformin HCL ER Contract identifies five PPVs. Cardinal Health of Dublin, Ohio is one of the designated DoD PPVs.

100. The governmental facilities served under the Metformin HCL ER Contract include the VA Medical Center located at 3200 Vine Street, Cincinnati, Ohio 45220; the VA Medical Center Dayton located at 4100 West Third Street, Dayton, Ohio 45428; the VA Medical Center located at 4337 Union Road, Middletown, Ohio 45005, and the VA Outpatient Clinic located at 512 South Burnett Road, Springfield, Ohio 45505.

101. The Metformin HCL ER Contract states that, "An award will be made to the responsible offeror whose proposal is determined to be technically acceptable and provides the lowest evaluated price. . . . To receive an acceptable rating for Technical Requirements, the offeror must accept all terms and conditions of the Statement of Work and Solicitation."

102. The Metformin HCL ER Contract provides that the Government may terminate the contract for cause if Defendant AvKARE fails to comply with any contract terms and conditions. In the event of such a termination for cause, Defendant AvKARE shall be liable to the Government for any and all rights and remedies provided by law.

103. The Metformin HCL ER Contract specifically requires Defendant AvKARE to

comply with DFARS 252.225-7021, Trade Agreements (OCT 2013).

104. The Metformin HCL ER Contract specifically states that, "This solicitation is subject to DFARS 225.4 - Trade Agreements as implemented by DFARS 252.225-7021 contained in this solicitation. Additionally, evaluations will be in accordance with DFARS Subpart 225.5."

105. DFARS 252.225-7021, Trade Agreements (OCT 2013), specifically requires Defendant AvKARE to deliver under this contract "only U.S.-made, qualifying country, or designated country end products . . . ." 48 C.F.R. 252.225-7021(c) (DFARS 252.225-7021(c)).

106. On January 12, 2015, Julie Roberts attested to the accuracy of AvKARE's Trade Agreements compliance; thereafter on December 17, 2015, February 17, 2016, and February 9, 2017, David Dunston attested to the accuracy of AvKARE's Trade Agreements compliance.

107. Specifically, on January 12, 2015, Julie Roberts, executed the Trade Agreements certification for AvKARE for the time period of January 12, 2015 through January 12, 2016, certifying on behalf of AvKARE that each end product (except those listed) is a U.S.-made, qualifying country, or designated country end product. (No non-compliant supplies were listed).

108. On December 17, 2015, February 17, 2016, and February 9, 2017, David Dunston executed this same Trade Agreements Certificate for Defendant AvKARE for the respective one year period beginning on each of those dates.

109. By submission of its offer for the Metformin HCL ER Contract and in its annual certifications, AvKARE affirmed that its Trade Agreements representations were current, accurate, complete, applicable to this solicitation, and incorporated by reference.

110. However, the metformin HCL ER tablets Defendant AvKARE provides to

governmental entities under Contract No. SPE2D2-15-D-0015 are not U.S.-made, and are not qualifying country, or designated country end products under the definitions provided in DFARS provision 252.225-7021, Trade Agreements (OCT 2013).

111. The metformin HCL ER tablets supplied by Defendant AvKARE under the Metformin HCL ER Contract are an end product of a non-TAA designated country of origin.

112. In order to obtain the Metformin HCL ER Contract, additional option years under that contract, and payments pursuant to that contract, Defendant AvKARE falsely represented that the metformin HCL ER it was selling was a "U.S.-made, qualifying country, or designated country end product."

113. Because the metformin HCL ER tablets distributed by Defendant AvKARE are not a product of a TAA designated country, they are ineligible for Government procurement under the express terms of Contract No. SPE2D2-15-D-0015.

114. Defendant AvKARE falsely represented that the metformin HCL ER it supplied under Contract No. SPE2D2-15-D-0015 was a TAA-compliant product.

115. Defendant AvKARE's representations that the metformin HCL ER tablets supplied under Contract No. SPE2D2-15-D-0015 were made in the United States or in a TAA qualifying or designated country were false. AvKARE made these false representations "knowingly," as that term is defined in 31 U.S.C. § 3729(b)(1).

116. As specified in the Metformin HCL ER Contract, the Government would not have awarded the Metformin HCL ER Contract, or option years under that contract, to AvKARE and AvKARE would not have been paid any money for metformin HCL ER tablets if AvKARE had truthfully disclosed in its bid that the country of origin for the metformin HCL ER tablets was a

non-TAA country of origin.

117. All claims for payment for metformin HCL ER tablets supplied by Defendant AvKARE under Contract No. SPE2D2-15-D-0015 are false claims.

C. The Lamotrigine IR Contract: VA Contract No. VA797P-15-C-0013

118. On December 4, 2014, the VA issued Solicitation No. VA797P-15-R-0021 seeking offers to supply its requirements of lamotrigine IR tablets.

119. Lamotrigine IR is a generic version of the brand name drug LaMICtal. It is used to treat epileptic seizures and bipolar disorder (manic depression).

120. By making an offer on Solicitation No.VA797P-15-R-0021, Defendant AvKARE agreed to furnish and deliver lamotrigine IR tablets subject to the terms and conditions specified in the solicitation.

121. On February 9, 2015, Defendant AvKARE was awarded Contract No. VA797P-15-C-0013 to supply lamotrigine IR tablets to the VA pursuant to Solicitation No. VA797P-15-R-0021 (collectively the "**Lamotrigine IR Contract**").

122. The Lamotrigine IR Contract is a firm fixed price requirements contract whereby Defendant AvKARE agreed to supply lamotrigine IR tablets for distribution to VA, DoD, IHS, and BoP facilities, as well as to Federal Health Care Centers and to specified State Veterans Homes.

123. The Lamotrigine IR Contract is for one base year, with four one-year option years.

124. The Lamotrigine IR Contract has a contract award amount of $8,847,030.50. This award amount is an estimate of the total value of annual orders by the various Government facilities for this drug.

125. The effective date of the base year of the Lamotrigine IR Contract was March 16, 2015.

126. On February 26, 2016, the VA exercised the first one year option available under the Lamotrigine IR Contract, permitting governmental entities to place orders under that contract from March 16, 2016 through March 15, 2017.

127. On February 13, 2017, the VA exercised the second one year option available under the Lamotrigine IR Contract, permitting governmental entities to place orders under that contract from March 16, 2017 through March 15, 2018.

128. The products awarded under the Lamotrigine IR Contract are ordered and distributed through the PPV Program.

129. The Lamotrigine IR Contract specifies that PPVs will accept Government orders for lamotrigine IR tablets and payment for such orders on behalf of Defendant AvKARE.

130. The Lamotrigine IR Contract identifies one VA PPV and five DoD PPVs. Cardinal Health of Dublin, Ohio is one of the designated DoD PPVs.

131. The governmental facilities served under the Lamotrigine IR Contract include the VA Medical Center located at 3200 Vine Street, Cincinnati, Ohio 45220; the VA Medical Center Dayton located at 4100 West Third Street, Dayton, Ohio 45428; the VA Medical Center located at 4337 Union Road, Middletown, Ohio 45005, and the VA Outpatient Clinic located at 512 South Burnett Road, Springfield, Ohio 45505.

132. The Lamotrigine IR Contract provides that all delivery orders under that contract "are subject to the terms and conditions of this contract."

133. The Lamotrigine IR Contract states that, "A contract will be awarded to the

responsible offeror that submits an offer meeting the solicitation requirements, and is the lowest price technically acceptable offer."

134. The Lamotrigine IR Contract provides that the Government may terminate the contract for cause if Defendant AvKARE fails to comply with any contract terms and conditions. In the event of such a termination for cause, Defendant AvKARE shall be liable to the Government for any and all rights and remedies provided by law.

135. The Lamotrigine IR Contract specifically requires Defendant AvKARE to comply with FAR provision 52.225-5, Trade Agreements (NOV 2013) (19 U.S.C. § 2501, *et seq*., 19 U.S.C. § 3301 note).

136. The Lamotrigine IR Contract also specifically requires Defendant AvKARE to certify that "each end product . . . is a U.S.-made, designated country end product, as defined in the clause of this solicitation entitled 'Trade Agreements'" and to list non-compliant end products. This provision of the Lamotrigine IR Contract also expressly states that, "The Government will consider for award only offers of U.S.-made or designated country end products unless the Contracting Officer determines that there are no offers for such products or that the offers for such products are insufficient to fulfill the requirements of the solicitation."[9]

137. Defendant AvKARE is required to certify Trade Agreements compliance on an annual basis.

138. On January 12, 2015, Julie Roberts attested to the accuracy of AvKARE's Trade Agreements compliance and made these annual certifications; thereafter on December 17, 2015, February 17, 2016, and February 9, 2017, David Dunston attested to the accuracy of AvKARE's

[9] No such determinations were made by the Contracting Officer.

Trade Agreements compliance and made these annual certifications.

139. Specifically, on January 12, 2015, Julie Roberts executed the Trade Agreements certification for Defendant AvKARE for the time period of January 12, 2015 through January 12, 2016, certifying on behalf of AvKARE that each end product (except those listed) is a U.S.-made or designated country end product. (No non-compliant end products were listed).

140. On December 17, 2015, February 17, 2016, and February 9, 2017, David Dunston executed this same Trade Agreements Certificate for Defendant AvKARE for the respective one year period beginning on each of those dates.

141. By submission of its offer for the Lamotrigine IR Contract, and in its annual certifications, AvKARE verified that its Trade Agreements certification was current, accurate, complete, applicable to this solicitation, and incorporated by reference.

142. However, the lamotrigine IR tablets Defendant AvKARE provides to governmental entities under Contract No. VA797P-15-C-0013 are not U.S.-made or designated country end products as defined in FAR provision 52.225-5, Trade Agreements (NOV 2013).

143. The lamotrigine IR tablets supplied by Defendant AvKARE under the Lamotrigine IR Contract are end products of India which is a non-TAA designated country of origin.

144. In order to obtain the Lamotrigine IR Contract, additional option years under that contract, and payments pursuant to that contract, Defendant AvKARE falsely certified that the lamotrigine IR it was selling was a "U.S.-made or designated country end product."

145. Because the lamotrigine IR tablets distributed by Defendant AvKARE are not a product of a TAA-designated country of origin, they are ineligible for Government procurement

under the express terms of Contract No. VA797P-15-C-0013.

146. Defendant AvKARE falsely represented that the lamotrigine IR it supplied under Contract No. VA797P-15-C-0013 was a TAA-compliant product.

147. Defendant AvKARE's certifications that the lamotrigine IR tablets supplied under Contract No. VA797P-15-C-0013 were made in the United States or in a TAA "designated country" were false. AvKARE made these false certifications "knowingly," as that term is defined 31 U.S.C § 3729(b)(1).

148. As specified in the Lamotrigine IR Contract and reiterated in the Trade Agreements Certificate, the Government would not have awarded the Lamotrigine IR Contract, or option years under that contract, to AvKARE and AvKARE would not have been paid any money for lamotrigine IR tablets if AvKARE had truthfully disclosed in its bid that the country of origin for the lamotrigine IR tablets was a non-TAA country of origin.

149. All claims for payment for lamotrigine IR tablets supplied by Defendant AvKARE under Contract No. VA797P-15-C-0013 are false claims.

D. The Ibuprofen Contract: DLA Contract No. SPE2D2-15-D-0022

150. On January 23, 2015, the DLA issued Solicitation No. SPE2D2-15-R-0005 seeking offers to supply its requirements of ibuprofen tablets.

151. Ibuprofen is a generic version of the brand name drugs Advil, Midol IB, and Motrin IB. It is a nonsteroidal anti-inflammatory drug (NSAID) that is used to reduce fever and treat pain or inflammation caused by many conditions such as headache, toothache, back pain, arthritis, menstrual cramps, or minor injury.

152. By making an offer on Solicitation No. SPE2D2-15-R-0005, Defendant AvKARE

agreed to furnish and deliver ibuprofen tablets subject to the terms and conditions specified in the solicitation.

153. On May 6, 2015, Defendant AvKARE was awarded Contract No. SPE2D2-15-D-0022 to supply ibuprofen tablets to the DLA pursuant to Solicitation No. SPE2D2-15-R-0005 (collectively the "**Ibuprofen Contract**").

154. The Ibuprofen Contract is a firm fixed price requirements contract whereby Defendant AvKARE agreed to supply ibuprofen tablets for distribution to Federal Government entities including the VA, DoD, IHS, and BoP.

155. The Ibuprofen Contract is for one base year, with four one-year option years.

156. The Ibuprofen Contract has a contract award amount of $19,798,073.95. This award is an estimate of the total value of all annual orders by the various Government facilities for this drug.

157. The effective date of the base year of the Ibuprofen Contract was May 6, 2015.

158. On May 4, 2016, the DLA exercised the first one year option available under the Ibuprofen Contract, permitting governmental entities to continue placing orders under that contract.

159. The Ibuprofen Contract specifies that Defendant AvKARE, as the awarded contractor, consents to allow VA and DoD prime vendors to distribute the listed products at the prices established in that contract.

160. The Ibuprofen Contract requires Defendant AvKARE to provide the products specified in the schedule at the prices established to all eligible DoD, VA, BoP and IHS customers.

161. The Ibuprofen Contract establishes a national supply source, in accordance with FAR 52.216-21 Requirements, to provide the drugs listed in the schedule for purchase by DLA and VA customers through the PPV.

162. The Ibuprofen Contract requires Defendant AvKARE to accept orders from designated PPVs at the prices agreed to under the contract and to deliver ibuprofen tablets to PPVs for distribution to DoD and VA medical treatment facilities, formularies, and eligible Government beneficiaries.

163. The Ibuprofen Contract requires Defendant AvKARE to establish a business relationship with the PPVs.

164. The Ibuprofen Contract identifies five PPVs. Cardinal Health of Dublin, Ohio is one of the designated DoD PPVs.

165. The governmental facilities served under the Ibuprofen Contract include the VA Medical Center located at 3200 Vine Street, Cincinnati, Ohio 45220; the VA Medical Center Dayton located at 4100 West Third Street, Dayton, Ohio 45428; the VA Medical Center located at 4337 Union Road, Middletown, Ohio 45005, and the VA Outpatient Clinic located at 512 South Burnett Road, Springfield, Ohio 45505.

166. The Ibuprofen Contract states that, "An award will be made to the responsible offeror whose proposal is determined to be technically acceptable and provides the lowest evaluated price." In addition, the Ibuprofen Contract specifies that "[t]o receive an acceptable rating for Technical Requirements, the offeror must accept all terms and conditions of the Statement of Work and Solicitation."

167. The Ibuprofen Contract provides that the Government may terminate the contract

for cause if Defendant AvKARE fails to comply with any contract terms and conditions. In the event of such a termination for cause, Defendant AvKARE shall be liable to the Government for any and all rights and remedies provided by law.

168. The Ibuprofen Contract specifically requires Defendant AvKARE to comply with DFARS 252.225-7021, Trade Agreements (OCT 2013) (19 U.S.C. §§ 2501-2518 and 19 U.S.C. § 3301 note).

169. The Ibuprofen Contract specifically states: "This solicitation is subject to DFARS 225.4 - Trade Agreements as implemented by DFARS 252.225-7021 contained in this solicitation. Additionally, evaluations will be in accordance with DFARS Subpart 225.5."

170. DFARS 252.225-7021, Trade Agreements (OCT 2013), specifically requires Defendant AvKARE to deliver under this contract "only U.S.-made or designated country end products . . . ." 48 C.F.R. 252.225-7021(c) (DFARS 252.225-7021(c)).

171. On January 12, 2015, Julie Roberts attested to the accuracy of AvKARE's Trade Agreements compliance; thereafter on December 17, 2015, February 17, 2016, and February 9, 2017, David Dunston attested to the accuracy of AvKARE's Trade Agreements compliance.

172. Specifically, on January 12, 2015, Julie Roberts executed the Trade Agreements certification for Defendant AvKARE for the time period of January 12, 2015 through January 12, 2016, certifying on behalf of AvKARE that each end product (except those listed) is a U.S.-made or designated country end product. (No non-compliant supplies were listed).

173. On December 17, 2015, February 17, 2016, and February 9, 2017, David Dunston executed this same Trade Agreements Certificate for Defendant AvKARE for the respective one year period beginning on each of those dates.

174. By submission of its offer for the Ibuprofen Contract and in its annual certifications, AvKARE affirmed that its Trade Agreements representations were current, accurate, complete, applicable to this solicitation, and incorporated by reference.

175. However, the ibuprofen tablets Defendant AvKARE provides to governmental entities under Contract No. SPE2D2-15-D-0022 are not U.S.-made, and are not qualifying country or designated country end products under the definitions provided in DFARS provision 252.225-7021, Trade Agreements (Nov 2013).

176. The ibuprofen tablets supplied by Defendant AvKARE under the Ibuprofen Contract are end products of a non-TAA designated country of origin.

177. In order to obtain the Ibuprofen Contract, additional option years under that contract, and payments pursuant to that contract, Defendant AvKARE falsely represented that the ibuprofen it was selling was a "U.S.-made, qualifying country, or designated country end product."

178. Because the ibuprofen tablets distributed by Defendant AvKARE are not a product of a TAA-designated country of origin, they are ineligible for Government procurement under the express terms of Contract No. SPE2D2-15-D-0022.

179. Defendant AvKARE falsely represented that the ibuprofen it supplied under Contract No. SPE2D2-15-D-0022 was a TAA-compliant product.

180. Defendant AvKARE's representations that the ibuprofen tablets supplied under Contract No. SPE2D2-15-D-0022 were made in the United States or in a TAA qualifying or designated country were false. AvKARE made these false representations "knowingly," as that term is defined in 31 U.S.C. § 3729(b)(1).

181. As specified in the Ibuprofen Contract, the Government would not have awarded the Ibuprofen Contract, or option years under that contract, to AvKARE and AvKARE would not have been paid any money for ibuprofen tablets if AvKARE had truthfully disclosed in its bid that the country of origin for the ibuprofen tablets was a non-TAA country of origin.

182. All claims for payment for ibuprofen tablets supplied by Defendant AvKARE under Contract No. SPE2D2-15-D-0022 are false claims.

E. The Metaxalone Contract: DLA Contract No. SPE2D2-16-D-0040

183. On January 14, 2016, the DLA issued Solicitation No. SPE2D2-16-R-0003 seeking offers to supply its requirements of metaxalone tablets.

184. Metaxalone is a generic version of the brand name drug Skelaxin. It is used to treat skeletal muscle conditions such as pain or injury.

185. By making an offer on Solicitation No. SPE2D2-1-R-0003, Defendant AvKARE agreed to furnish and deliver metaxalone tablets subject to the terms and conditions specified in the solicitation.

186. On June 16, 2016, Defendant AvKARE was awarded Contract No. SPE2D2-16-D-0040 to supply metaxalone tablets to the DLA pursuant to Solicitation No. SPE2D2-16-R-0003 (collectively the "**Metaxalone Contract**").

187. The Metaxalone Contract is a firm fixed price requirements contract whereby Defendant AvKARE agreed to supply metaxalone tablets for distribution to Federal Government entities including the VA, DoD, IHS, and BoP.

188. The Metaxalone Contract is for one base year, with four one-year option years.

189. The Metaxalone Contract has a contract award amount of $13,506,257.60. This

award is an estimate of the total value of all annual orders by the various Government facilities for this drug.

190. The effective date of the base year of the Metaxalone Contract was June 16, 2016.

191. The Metaxalone Contract specifies that Defendant AvKARE, as the awarded contractor, consents to allow VA and DoD PPVs to distribute the listed products at the prices established in that contract.

192. The Metaxalone Contract requires Defendant AvKARE to provide the products specified in the schedule at the prices established to all eligible DoD, VA, BoP and IHS customers.

193. The Metaxalone Contract establishes a national supply source, in accordance with FAR 52.216-21 Requirements, to provide the drugs listed in the schedule for purchase by DLA and VA customers through the PPV.

194. The Metaxalone Contract requires Defendant AvKARE to accept orders from designated PPVs at the prices agreed to under the contract and to deliver metaxalone tablets to PPVs for distribution to DoD and VA medical treatment facilities, formularies, and eligible Government beneficiaries.

195. The Metaxalone Contract requires Defendant AvKARE to establish a business relationship with the PPVs.

196. The Metaxalone Contract identifies five PPVs. Cardinal Health of Dublin, Ohio is one of the designated DoD PPVs.

197. The governmental facilities served under the Metaxalone Contract include the VA Medical Center located at 3200 Vine Street, Cincinnati, Ohio 45220; the VA Medical Center

Dayton located at 4100 West Third Street, Dayton, Ohio 45428; the VA Medical Center located at 4337 Union Road, Middletown, Ohio 45005, and the VA Outpatient Clinic located at 512 South Burnett Road, Springfield, Ohio 45505.

198. The Metaxalone Contract states that, "An award will be made to the responsible offeror whose proposal is determined to be technically acceptable and provides the lowest evaluated price. . . . To receive an acceptable rating for Technical Requirements, the offeror must accept all terms and conditions of the Statement of Work and Solicitation."

199. The Metaxalone Contract provides that the Government may terminate the contract for cause if Defendant AvKARE fails to comply with any contract terms and conditions. In the event of such a termination for cause, Defendant AvKARE shall be liable to the Government for any and all rights and remedies provided by law.

200. The Metaxalone Contract specifically requires Defendant AvKARE to comply with DFARS 252.225-7021, Trade Agreements (OCT 2015).

201. The Metaxalone Contract specifically states: "This solicitation is subject to DFARS 225.4 - Trade Agreements as implemented by DFARS 252.225-7021 contained in this solicitation. Additionally, evaluations will be in accordance with DFARS Subpart 225.5."

202. DFARS 252.225-7021, Trade Agreements (OCT 2015), specifically requires Defendant AvKARE to deliver under this contract "only U.S.-made, qualifying country, or designated country end products . . . ." 48 C.F.R. 252.225-7021(c) (DFARS 252.225-7021(c)).

203. On February 17, 2016 and February 9, 2017, David Dunston attested to the accuracy of AvKARE's Trade Agreements compliance.

204. Specifically, on February 17, 2016, David Dunston executed the Trade

Agreements certification for Defendant AvKARE for the time period of February 17, 2016 through February 17, 2017, certifying on behalf of AvKARE that each end product (except those listed) is a U.S.-made, qualifying country, or designated country end product. (No non-compliant supplies were listed).

205. On February 9, 2017, David Dunston executed this same Trade Agreements Certificate for Defendant AvKARE for the one year period beginning on that date.

206. By submission of its offer for the Metaxalone Contract and in its annual certifications, AvKARE affirmed that its Trade Agreements representations were current, accurate, complete, applicable to this solicitation, and incorporated by reference.

207. However, the metaxalone tablets Defendant AvKARE provides to governmental entities under Contract No. SPE2D2-16-D-0040 are not U.S.-made, and are not qualifying country or designated country end products under the definitions provided in DFARS provision 252.225-7021, Trade Agreements (OCT 2015).

208. The metaxalone tablets supplied by Defendant AvKARE under the Metaxalone Contract are end products of a non-TAA designated country of origin.

209. In order to obtain the Metaxalone Contract, additional option years under that contract, and payments pursuant to that contract, Defendant AvKARE falsely represented that the metaxalone it was selling was a "U.S.-made, qualifying country, or designated country end product."

210. Because the metaxalone tablets distributed by Defendant AvKARE are not a product of a TAA designated country, they are ineligible for Government procurement under the express terms of Contract No. SPE2D2-16-D-0040.

211. Defendant AvKARE falsely represented that the metaxalone it supplied under Contract No. SPE2D2-16-D-0040 was a TAA-compliant product.

212. Defendant AvKARE's representations that the metaxalone tablets supplied under Contract No. SPE2D2-16-D-0040 were made in the United States or in a TAA qualifying or designated country were false. AvKARE made these false representations "knowingly," as that term is defined in 31 U.S.C. § 3729(b)(1).

213. As specified in the Metaxalone Contract, the Government would not have awarded the Metaxalone Contract, or option years under that contract, to AvKARE and AvKARE would not have been paid any money for metaxalone tablets if AvKARE had truthfully disclosed in its bid that the country of origin for the metaxalone tablets was a non-TAA country of origin.

214. All claims for payment for metaxalone tablets supplied by Defendant AvKARE under Contract No. SPE2D2-16-D-0040 are false claims.

F. The Trazodone HCL Contract: DLA Contract No. SPE2D2-16-D-0041

215. On February 11, 2016, the DLA issued Solicitation No. SPE2D2-16-R-0002 seeking offers to supply its requirements of trazodone HCL tablets.

216. Trazodone hydrochloride is a generic version of the brand name drugs Oleptro, Desyrel, and Desyrel Dividose. It is used to treat major depressive disorder.

217. By making an offer on Solicitation No. SPE2D2-16-R-0002, Defendant AvKARE agreed to furnish and deliver trazodone HCL tablets subject to the terms and conditions specified in the solicitation.

218. On July 19, 2016, Defendant AvKARE was awarded Contract No. SPE2D2-16-D-

0041 to supply trazodone HCL tablets to the DLA pursuant to Solicitation No. SPE2D2-16-R-0002 (collectively the "**Trazodone HCL Contract**").

219. The Trazodone HCL Contract is a firm fixed price requirements contract whereby Defendant AvKARE agreed to supply trazodone HCL tablets for distribution to Federal Government entities including the VA, DoD, IHS, and BoP.

220. The Trazodone HCL Contract is for one base year, with four one-year option years.

221. The Trazodone HCL Contract has a contract award amount of $31,732,971.40. This award amount is an estimate of the total value of all annual orders by the various Government facilities for this drug.

222. The effective date of the base year of the Trazodone HCL Contract was July 19, 2016.

223. The Trazodone HCL Contract specifies that Defendant AvKARE, as the awarded contractor, consents to allow VA and DoD prime vendors to distribute the listed products at the prices established in that contract.

224. The Trazodone HCL Contract requires Defendant AvKARE to provide the products specified in the schedule at the prices established to all eligible DoD, VA, BoP and IHS customers.

225. The Trazodone HCL Contract establishes a national supply source, in accordance with FAR 52.216-21 Requirements, to provide the drugs listed in the schedule for purchase by DLA and VA customers through the PPV.

226. The Trazodone HCL Contract requires Defendant AvKARE to accept orders from

designated PPVs at the prices agreed to under the contract and to deliver trazodone HCL tablets to PPVs for distribution to DoD and VA medical treatment facilities, formularies, and eligible Government beneficiaries.

227. The Trazodone HCL Contract requires Defendant AvKARE to establish a business relationship with the PPVs.

228. The Trazodone HCL Contract identifies five PPVs. Cardinal Health of Dublin, Ohio is one of the designated DoD PPVs.

229. The governmental facilities served under the Trazodone HCL Contract include the VA Medical Center located at 3200 Vine Street, Cincinnati, Ohio 45220; the VA Medical Center Dayton located at 4100 West Third Street, Dayton, Ohio 45428; the VA Medical Center located at 4337 Union Road, Middletown, Ohio 45005, and the VA Outpatient Clinic located at 512 South Burnett Road, Springfield, Ohio 45505.

230. The Trazodone HCL Contract states that, "An award will be made to the responsible offeror whose proposal is determined to be technically acceptable and provides the lowest evaluated aggregate price."

231. In addition, the Trazodone HCL Contract specifies that "[t]o receive an acceptable rating for Technical Requirements, the offeror must accept all terms and conditions of the Statement of Work and Solicitation."

232. The Trazodone HCL Contract provides that the Government may terminate the contract for cause if Defendant AvKARE fails to comply with any contract terms and conditions. In the event of such a termination for cause, Defendant AvKARE shall be liable to the Government for any and all rights and remedies provided by law.

233. The Trazodone HCL Contract specifically requires Defendant AvKARE to comply with DFARS 252.225-7021, Trade Agreements (JUN 2016) (19 U.S.C. §§ 2501-2518 and 19 U.S.C. § 3301 note).

234. The Trazodone HCL Contract specifically states: "This solicitation is subject to DFARS 225.4 - Trade Agreements as implemented by DFARS 252.225-7021 contained in this solicitation. Additionally, evaluations will be in accordance with DFARS Subpart 225.5."

235. DFARS 252.225-7021, Trade Agreements (JUN 2016), specifically requires Defendant AvKARE to deliver under this contract "only U.S.-made, qualifying country, or designated country end products . . . ." 48 C.F.R. 252.225-7021(c) (DFARS 252.225-7021(c)).

236. On February 17, 2016 and February 9, 2017, David Dunston attested to the accuracy of AvKARE's Trade Agreements compliance.

237. Specifically, on February 17, 2016, David Dunston executed the Trade Agreements certification for Defendant AvKARE for the time period of February 17, 2016 through February 17, 2017, certifying on behalf of AvKARE that each end product (except those listed) is a U.S.-made, qualifying country, or designated country end product. (No non-compliant supplies were listed).

238. On February 9, 2017, David Dunston executed this same Trade Agreements Certificate for Defendant AvKARE for the one year period beginning on that date.

239. By submission of its offer for the Trazodone HCL Contract and in its annual certifications, AvKARE affirmed that its Trade Agreements certification was current, accurate, complete, applicable to this solicitation, and incorporated by reference.

240. However, the trazodone HCL tablets Defendant AvKARE provides to

governmental entities under Contract No. SPE2D2-16-D-0041 are not U.S.-made, and are not qualifying country or designated country end products under the definitions provided in DFARS provision 252.225-7021, Trade Agreements (JUN 2016).

241. The trazodone HCL tablets supplied by Defendant AvKARE under the Trazodone HCL Contract are end products of a non-TAA designated country of origin.

242. In order to obtain the Trazodone HCL Contract, additional option years under that contract, and payments pursuant to that contract, Defendant AvKARE falsely represented that the trazadone HCL it was selling was a "U.S.-made, qualifying country, or designated country end product."

243. Because the trazodone HCL tablets distributed by Defendant AvKARE are not a product of a TAA-designated county of origin, they are ineligible for Government procurement under the express terms of Contract No. SPE2D2-16-D-0041.

244. Defendant AvKARE falsely represented that the trazodone HCL it supplied under Contract No. SPE2D2-16-D-0041 was a TAA-compliant product.

245. Defendant AvKARE's representations that the trazodone HCL tablets supplied under Contract No. SPE2D2-16-D-0041 were made in the United States or in a TAA qualifying or designated country were false. AvKARE made these false representations "knowingly," as that term is defined in 31 U.S.C. § 3729(b)(1).

246. As specified in the Trazodone HCL Contract, the Government would not have awarded the Trazodone HCL Contract, or option years under that contract, to AvKARE and AvKARE would not have been paid any money for trazodone HCL tablets if AvKARE had truthfully disclosed in its bid that the country of origin for the trazodone HCL tablets was a non-

TAA country of origin.

247. All claims for payment for trazodone HCL tablets supplied by Defendant AvKARE under Contract No. SPE2D2-16-D-0041 are false claims.

G. The Naproxen Contract: VA Contract No. VA797P-13-C-0016

248. On October 26, 2012, the VA issued Solicitation No. VA797P-12-R-0032 seeking *inter alia* offers to supply its requirements of naproxen tablets.[10]

249. Naproxen is a generic version of the brand name drug Aleve. It is an NSAID (nonsteroidal anti-inflammatory drug) that is used to treat pain or inflammation caused by conditions such as arthritis, ankylosing spondylitis, tendinitis, bursitis, gout, or menstrual cramps.

250. By making an offer on Solicitation No. VA797P-12-R-0032, Defendant AvKARE agreed to furnish and deliver naproxen tablets subject to the terms and conditions specified in the solicitation.

251. On December 27, 2012, Defendant AvKARE was awarded Contract No. VA797P-13-C-0016 to supply naproxen tablets to the VA pursuant to Solicitation No. VA797P-12-R-0032 (collectively the "**Naproxen Contract**").

252. The Naproxen Contract is a firm fixed price requirements contract whereby Defendant AvKARE agreed to supply naproxen tablets for distribution to VA, DoD, IHS, and BoP facilities, as well as to Federal Health Care Centers and to specified State Veteran Homes.

253. The Naproxen Contract is for one base year, with four one-year option years.

[10] That solicitation also sought offers to supply other drugs.

254. The Naproxen Contract has a contract award amount of $2,185,078.45. This award amount is an estimate of the total value of all annual orders by the various Government facilities for this drug.

255. The effective date of the base year of the Naproxen Contract was January 3, 2013.

256. On January 27, 2013, the VA exercised the first one year option available under the Naproxen Contract, permitting governmental entities to place orders under that contract from January 3, 2014 through January 2, 2015.

257. On December 15, 2014, the VA exercised the second one year option available under the Naproxen Contract, permitting governmental entities to place orders under that contract from January 3, 2015 through January 2, 2016.

258. On December 28, 2015, the VA exercised the third one year option available under the Naproxen Contract, permitting governmental entities to place orders under that contract from January 3, 2016 through January 2, 2017.

259. On November 16, 2016, the VA exercised the fourth and final one year option available under the Naproxen Contract, permitting governmental entities to place orders under that contract from January 3, 2017 through January 2, 2018.

260. The products awarded under the Naproxen Contract are ordered and distributed through the PPV Program.

261. The Naproxen Contract specifies that PPVs will accept Government orders of naproxen and payment for such orders on behalf of Defendant AvKARE.

262. The Naproxen Contract identifies one VA PPV and five DoD PPVs. Cardinal Health of Dublin, Ohio is one of the designated DoD PPVs.

263. The governmental facilities served under the Naproxen Contract include the VA Medical Center located at 3200 Vine Street, Cincinnati, Ohio 45220; the VA Medical Center Dayton located at 4100 West Third Street, Dayton, Ohio 45428; the VA Medical Center located at 4337 Union Road, Middletown, Ohio 45005, and the VA Outpatient Clinic located at 512 South Burnett Road, Springfield, Ohio 45505.

264. The Naproxen Contract states that, "Contracts will be awarded to the responsible offeror that submits offers meeting the solicitation requirements, and are the lowest price technically acceptable."

265. The Naproxen Contract provides that the Government may terminate the contract for cause if Defendant AvKARE fails to comply with any contract terms and conditions. In the event of such a termination for cause, Defendant AvKARE shall be liable to the Government for any and all rights and remedies provided by law.

266. The Naproxen Contract provides that all delivery orders under that contract "are subject to the terms and conditions of this contract."

267. The Naproxen Contract specifically requires Defendant AvKARE to comply with FAR provision 52.225-5, Trade Agreements (MAY 2012) (19 U.S.C. § 2501, *et seq*., 19 U.S.C. § 3301 note).

268. The Naproxen Contract also specifically requires Defendant AvKARE to certify that "each end product . . . is a U.S.-made, designated country end product, as defined in the clause of this solicitation entitled 'Trade Agreements'" and to list non-compliant end products. This provision of the Naproxen Contract also expressly states that "The Government will consider for award only offers of U.S.-made or designated country end products unless the

Contracting Officer determines that there are no offers for such products or that the offers for such products are insufficient to fulfill the requirements of the solicitation."[11]

269. Defendant AvKARE is required to certify Trade Agreements compliance on an annual basis.

270. On January 12, 2015, Julie Roberts attested to the accuracy of AvKARE's Trade Agreements compliance and made these annual certifications; thereafter on December 17, 2015, February 17, 2016, and February 9, 2017, David Dunston attested to the accuracy of AvKARE's Trade Agreements compliance and made these annual certifications.

271. Specifically, on January 12, 2015, Julie Roberts, attested to the accuracy of AvKARE's certification and executed the Trade Agreements certification for AvKARE for the time period of January 12, 2015 through January 12, 2016, certifying on behalf of AvKARE that each end product (except those listed) is a U.S.-made or designated country end product. (No non-compliant end products were listed).

272. On December 17, 2015, February 17, 2016, and February 9, 2017, David Dunston executed this same Trade Agreements Certificate for Defendant AvKARE for the respective one year period beginning on each of those dates.

273. By submission of its offer for the Naproxen Contract, AvKARE verified that its Trade Agreements certification was current, accurate, complete, and applicable to this solicitation, and incorporated by reference.

274. However, the naproxen tablets Defendant AvKARE provides to governmental

[11] No such determinations were made by the Contracting Officer.

entities under Contract No. VA797P-13-C-0016 are not U.S.-made or designated country end products as defined in FAR provision 52.225-5, Trade Agreements (MAY 2012).

275. The naproxen tablets supplied by Defendant AvKARE under the Naproxen Contract are end products of a non-TAA designated country of origin.

276. In order to obtain the Naproxen Contract, additional option years under that contract, and payments pursuant to that contract, Defendant AvKARE falsely certified that the naproxen it was selling was a "U.S.-made or designated country end product."

277. Because the naproxen tablets distributed by Defendant AvKARE are not a product of a TAA-designated country of origin, they are ineligible for Government procurement under the express terms of Contract No. VA797P-13-C-0016.

278. Defendant AvKARE falsely represented that the naproxen it supplied under Contract No. VA797P-13-C-0016 was a TAA-compliant product.

279. Defendant AvKARE's certifications that the naproxen tablets supplied under Contract No. VA797P-13-C-0016 were made in the United States or in a TAA "designated country" were false. AvKARE made these false certifications "knowingly," as that term is defined 31 U.S.C § 3729(b)(1).

280. As specified in the Naproxen Contract and reiterated in the Trade Agreements Certificate, the Government would not have awarded the Naproxen Contract, or option years under that contract, to Defendant AvKARE and AvKARE would not have been paid any money for naproxen tablets if AvKARE had truthfully disclosed in its bid that the country of origin for the naproxen tablets was a non-TAA country of origin.

281. All claims for payment for naproxen tablets supplied by Defendant AvKARE

under Contract No. VA797P-13-C-0016 are false claims.

H. The Fludrocortisone Acetate Contract: VA Contract No. VA797P-15-C-0049

282. On May 18, 2015, the VA issued Solicitation No. VA797P-15-R-0065 seeking offers to supply its requirements of fludrocortisone acetate tablets.

283. Fludrocortisone Acetate is a generic version of the brand name drug Florinef Acetate. It is a steroid that prevents the release of substances in the body that cause inflammation. It is used to treat conditions in which the body does not produce enough of its own steroids, such as Addison's disease, and salt-losing adrenogenital syndrome.

284. By making an offer on Solicitation No. VA797P-15-R-0065, Defendant AvKARE agreed to furnish and deliver fludrocortisone acetate tablets subject to the terms and conditions specified in the solicitation.

285. On August 5, 2015, Defendant AvKARE was awarded Contract No. VA797P-15-C-0049 to supply fludrocortisone acetate tablets to the VA pursuant to Solicitation No. VA797P-15-R-0065 (collectively the "**Fludrocortisone Acetate Contract**").

286. The Fludrocortisone Acetate Contract is a firm fixed price requirements contract whereby Defendant AvKARE agreed to supply fludrocortisone acetate tablets for distribution to VA, DoD, IHS, and BoP facilities, as well as to Federal Health Care Centers and to specified State Veteran Homes.

287. The Fludrocortisone Acetate Contract is for one base year, with four one-year option years.

288. The Fludrocortisone Acetate Contract has a contract award amount of $5,057,774.00. This award amount is an estimate of the total value of all annual orders by the

various Government facilities for this drug.

289. The effective date of the base year of the Fludrocortisone Acetate Contract was October 26, 2015.

290. On September 28, 2016, the VA exercised the first one year option available under the Fludrocortisone Acetate Contract, permitting governmental entities to place orders under that contract from October 26, 2016 through October 25, 2017.

291. On September 29, 2017, the VA exercised the second one year option available under the Fludrocortisone Acetate Contract, permitting governmental entities to place orders under that contract from October 26, 2017 through October 25, 2018.

292. The products awarded under the Fludrocortisone Acetate Contract are ordered and distributed through the PPV Program.

293. The Fludrocortisone Acetate Contract specifies that PPVs will accept Government orders of fludrocortisone acetate and payment for such orders on behalf of Defendant AvKARE.

294. The Fludrocortisone Acetate Contract identifies one VA PPV and five DoD PPVs. Cardinal Health of Dublin, Ohio is one of the designated DoD PPVs.

295. The governmental facilities served under the Fludrocortisone Acetate Contract include the VA Medical Center located at 3200 Vine Street, Cincinnati, Ohio 45220; the VA Medical Center Dayton located at 4100 West Third Street, Dayton, Ohio 45428; the VA Medical Center located at 4337 Union Road, Middletown, Ohio 45005, and the VA Outpatient Clinic located at 512 South Burnett Road, Springfield, Ohio 45505.

296. The Fludrocortisone Acetate Contract states that, “A contract will be awarded to the responsible offeror that submits an offer meeting the solicitation requirements, and is the

lowest price technically acceptable offer."

297. The Fludrocortisone Acetate Contract provides that the Government may terminate the contract for cause if Defendant AvKARE fails to comply with any contract terms and conditions. In the event of such a termination for cause, Defendant AvKARE shall be liable to the Government for any and all rights and remedies provided by law.

298. The Fludrocortisone Acetate Contract provides that all delivery orders under that contract "are subject to the terms and conditions of this contract."

299. The Fludrocortisone Acetate Contract specifically requires Defendant AvKARE to comply with FAR provision 52.225-5, Trade Agreements (NOV 2013) (19 U.S.C. § 2501, *et seq*., 19 U.S.C. § 3301 note).

300. The Fludrocortisone Acetate Contract also specifically requires Defendant AvKARE to certify that "each end product . . . is a U.S.-made or designated country end product, as defined in the clause of this solicitation entitled 'Trade Agreements'" and to list non-compliant end products. This provision of the Fludrocortisone Acetate Contract also expressly states that "The Government will consider for award only offers of U.S.-made or designated country end products unless the Contracting Officer determines that there are no offers for such products or that the offers for such products are insufficient to fulfill the requirements of the solicitation."[12]

301. Defendant AvKARE is required to certify Trade Agreements compliance on an annual basis.

[12] No such determinations were made by the Contracting Officer.

302. On January 12, 2015, Julie Roberts attested to the accuracy of AvKARE's Trade Agreements compliance and made these annual certifications; thereafter on December 17, 2015, February 17, 2016, and February 9, 2017, David Dunston attested to the accuracy of AvKARE's Trade Agreements compliance and made these annual certifications.

303. Specifically, on January 12, 2015, Julie Roberts, attested to the accuracy of AvKARE's certification and executed the Trade Agreements certification for AvKARE for the time period of January 12, 2015 through January 12, 2016, certifying on behalf of AvKARE that each end product (except those listed) is a U.S.-made or designated country end product. (No non-compliant end products were listed).

304. On December 17, 2015, February 17, 2016, and February 9, 2017, David Dunston executed this same Trade Agreements Certificate for Defendant AvKARE for the respective one year period beginning on each of those dates.

305. By submission of its offer for the Fludrocortisone Acetate Contract, AvKARE verified that its Trade Agreements certification was current, accurate, complete, and applicable to this solicitation, and incorporated by reference.

306. However, the fludrocortisone acetate tablets Defendant AvKARE provides to governmental entities under Contract No. VA797P-15-C-0049 are not U.S.-made or designated country end products as defined in FAR provision 52.225-5, Trade Agreements (NOV 2013).

307. The fludrocortisone acetate tablets supplied by Defendant AvKARE under the Fludrocortisone Acetate Contract are end products of a non-TAA designated country of origin.

308. In order to obtain the Fludrocortisone Acetate Contract, additional option years under that contract, and payments pursuant to that contract, Defendant AvKARE falsely certified

that the fludrocortisone acetate it was selling was a "U.S.-made or designated country end product."

309. Because the fludrocortisone acetate tablets distributed by Defendant AvKARE are not a product of a TAA-designated country of origin, they are ineligible for Government procurement under the express terms of Contract No. VA797P-15-C-0049.

310. Defendant AvKARE falsely represented that the fludrocortisone acetate it supplied under Contract No. VA797P-15-C-0049 was a TAA-compliant product.

311. Defendant AvKARE's certifications that the fludrocortisone acetate tablets supplied under Contract No. VA797P-15-C-0049 were made in the United States or in a TAA "designated country" were false. AvKARE made these false certifications "knowingly," as that term is defined 31 U.S.C § 3729(b)(1).

312. As specified in the Fludrocortisone Acetate Contract and reiterated in the Trade Agreements Certificate, the Government would not have awarded the Fludrocortisone Acetate Contract, or option years under that contract, to Defendant AvKARE and AvKARE would not have been paid any money for fludrocortisone acetate tablets if AvKARE had truthfully disclosed in its bid that the country of origin for the fludrocortisone acetate tablets was a non-TAA country of origin.

313. All claims for payment for fludrocortisone acetate tablets supplied by Defendant AvKARE under Contract No. VA797P-15-C-0049 are false claims.

I. The Oxybutynin CL Contract: VA Contract No. VA797P-16-C-0044

314. On January 13, 2016, the VA issued Solicitation No. VA797P-16-R-0028 seeking offers to supply its requirements of oxybutynin CL tablets.

315. Oxybutynin CL is a generic version of the brand name drugs Ditropan XL and Urotrol. It is used to treat symptoms of overactive bladder, such as frequent or urgent urination, incontinence (urine leakage), and increased night-time urination.

316. By making an offer on Solicitation No. VA797P-16-R-0028, Defendant AvKARE agreed to furnish and deliver oxybutynin CL tablets subject to the terms and conditions specified in the solicitation.

317. On March 8, 2016, Defendant AvKARE was awarded Contract No. VA797P-16-C-0044 to supply oxybutynin CL tablets to the VA pursuant to Solicitation No. VA797P-16-R-0028 (collectively the "**Oxybutynin CL Contract**").

318. The Oxybutynin CL Contract is a firm fixed price requirements contract whereby Defendant AvKARE agreed to supply oxybutynin CL tablets for distribution to VA, DoD, IHS, and BoP facilities, as well as to Federal Health Care Centers and to specified State Veteran Homes.

319. The Oxybutynin CL Contract is for one base year, with four one-year option years.

320. The Oxybutynin CL Contract has a contract award amount of $19,516,971.00. This award amount is an estimate of the total value of all annual orders by the various Government facilities for this drug.

321. The effective date of the base year of the Oxybutynin CL Contract was May 9, 2016.

322. On May 1, 2017, the VA exercised the first one year option available under the Oxybutynin CL Contract, permitting governmental entities to place orders under that contract from May 9, 2017 through May 8, 2018.

323. The products awarded under the Oxybutynin CL Contract are ordered and distributed through the PPV Program.

324. The Oxybutynin CL Contract specifies that PPVs will accept Government orders of oxybutynin CL and payment for such orders on behalf of Defendant AvKARE.

325. The Oxybutynin CL Contract identifies one VA PPV and five DoD PPVs. Cardinal Health of Dublin, Ohio is one of the designated DoD PPVs.

326. The governmental facilities served under the Oxybutynin CL Contract include the VA Medical Center located at 3200 Vine Street, Cincinnati, Ohio 45220; the VA Medical Center Dayton located at 4100 West Third Street, Dayton, Ohio 45428; the VA Medical Center located at 4337 Union Road, Middletown, Ohio 45005, and the VA Outpatient Clinic located at 512 South Burnett Road, Springfield, Ohio 45505.

327. The Oxybutynin CL Contract states that, "A contract will be awarded to the responsible offeror that submits an offer meeting the solicitation requirements, and is the lowest price technically acceptable offer."

328. The Oxybutynin CL Contract provides that the Government may terminate the contract for cause if Defendant AvKARE fails to comply with any contract terms and conditions. In the event of such a termination for cause, Defendant AvKARE shall be liable to the Government for any and all rights and remedies provided by law.

329. The Oxybutynin CL Contract provides that all delivery orders under that contract "are subject to the terms and conditions of this contract."

330. The Oxybutynin CL Contract specifically requires Defendant AvKARE to comply with FAR provision 52.225-5, Trade Agreements (NOV 2013) (19 U.S.C. § 2501, *et seq*., 19

U.S.C. § 3301 note).

331. The Oxybutynin CL Contract also specifically requires Defendant AvKARE to certify that "each end product . . . is a U.S.-made or designated country end product, as defined in the clause of this solicitation entitled 'Trade Agreements'" and to list non-compliant end products. This provision of the Oxybutynin CL Contract also expressly states that "The Government will consider for award only offers of U.S.-made or designated country end products unless the Contracting Officer determines that there are no offers for such products or that the offers for such products are insufficient to fulfill the requirements of the solicitation."[13]

332. Defendant AvKARE is required to certify Trade Agreements compliance on an annual basis.

333. On December 17, 2015, February 17, 2016, and February 9, 2017, David Dunston attested to the accuracy of AvKARE's Trade Agreements compliance and made these annual certifications.

334. Specifically, on December 17, 2015, David Dunston attested to the accuracy of AvKARE's certification and executed the Trade Agreements certification for AvKARE for the time period of December 17, 2015 through December 17, 2016, certifying on behalf of AvKARE that each end product (except those listed) is a U.S.-made or designated country end product. (No non-compliant end products were listed).

335. On February 17, 2016, and February 9, 2017, David Dunston executed this same Trade Agreements Certificate for Defendant AvKARE for the respective one year period

[13] No such determinations were made by the Contracting Officer.

beginning on each of those dates.

336. By submission of its offer for the Oxybutynin CL Contract, AvKARE verified that its Trade Agreements certification was current, accurate, complete, and applicable to this solicitation, and incorporated by reference.

337. However, the oxybutynin CL tablets Defendant AvKARE provides to governmental entities under Contract No. VA797P-16-C-0044 are not U.S.-made or designated country end products as defined in FAR provision 52.225-5, Trade Agreements (NOV 2013).

338. The oxybutynin CL tablets supplied by Defendant AvKARE under the Oxybutynin CL Contract are end products of a non-TAA designated country of origin.

339. In order to obtain the Oxybutynin CL Contract, additional option years under that contract, and payments pursuant to that contract, Defendant AvKARE falsely certified that the oxybutynin CL it was selling was a "U.S.-made or designated country end product."

340. Because the oxybutynin CL tablets distributed by Defendant AvKARE are not a product of a TAA-designated country of origin, they are ineligible for Government procurement under the express terms of Contract No. VA797P-16-C-0044.

341. Defendant AvKARE falsely represented that the oxybutynin CL it supplied under Contract No. VA797P-16-C-0044 was a TAA-compliant product.

342. Defendant AvKARE's certifications that the oxybutynin CL tablets supplied under Contract No. VA797P-16-C-0044 were made in the United States or in a TAA "designated country" were false. AvKARE made these false certifications "knowingly," as that term is defined 31 U.S.C § 3729(b)(1).

343. As specified in the Oxybutynin CL Contract and reiterated in the Trade

Agreements Certificate, the Government would not have awarded the Oxybutynin CL Contract, or option years under that contract, to Defendant AvKARE and AvKARE would not have been paid any money for oxybutynin CL tablets if AvKARE had truthfully disclosed in its bid that the country of origin for the oxybutynin CL tablets was a non-TAA country of origin.

344. All claims for payment for oxybutynin CL tablets supplied by Defendant AvKARE under Contract No. VA797P-16-C-0044 are false claims.

J. The Venlafaxine HCL Contract: VA Contract No. VA797P-16-C-0060

345. On April 5, 2016, the VA issued Solicitation No. VA797P-16-R-0039 seeking offers to supply its requirements of venlafaxine HCL tablets.

346. Venlafaxine HCL is a generic version of the brand name drug Effexor. It is an antidepressant belonging to a group of drugs called selective serotonin and norepinephrine reuptake inhibitors (SSNRIs). It is used to treat major depressive disorder, anxiety, and panic disorder.

347. By making an offer on Solicitation No. VA797P-16-R-0039, Defendant AvKARE agreed to furnish and deliver venlafaxine HCL tablets subject to the terms and conditions specified in the solicitation.

348. On June 7, 2016, Defendant AvKARE was awarded Contract No. VA797P-16-C-0060 to supply venlafaxine HCL tablets to the VA pursuant to Solicitation No. VA797P-16-R-0039 (collectively the "**Venlafaxine HCL Contract**").

349. The Venlafaxine HCL Contract is a firm fixed price requirements contract whereby Defendant AvKARE agreed to supply venlafaxine HCL tablets for distribution to VA, DoD, IHS, and BoP facilities, as well as to Federal Health Care Centers and to specified State

Veteran Homes.

350. The Venlafaxine HCL Contract is for one base year, with four one-year option years.

351. The Venlafaxine HCL Contract has a contract award amount of $6,545,073.75. This award amount is an estimate of the total value of all annual orders by the various Government facilities for this drug.

352. The effective date of the base year of the Venlafaxine HCL Contract was August 28, 2016.

353. On July 24, 2017, the VA exercised the first one year option available under the Venlafaxine HCL Contract, permitting governmental entities to place orders under that contract from August 28, 2017 through August 27, 2018.

354. The products awarded under the Venlafaxine HCL Contract are ordered and distributed through the PPV Program.

355. The Venlafaxine HCL Contract specifies that PPVs will accept Government orders of venlafaxine HCL and payment for such orders on behalf of Defendant AvKARE.

356. The Venlafaxine HCL Contract identifies one VA PPV and five DoD PPVs. Cardinal Health of Dublin, Ohio is one of the designated DoD PPVs.

357. The governmental facilities served under the Venlafaxine HCL Contract include the VA Medical Center located at 3200 Vine Street ,Cincinnati, Ohio 45220; the VA Medical Center Dayton located at 4100 West Third Street, Dayton, Ohio 45428; the VA Medical Center located at 4337 Union Road, Middletown, Ohio 45005, and the VA Outpatient Clinic located at 512 South Burnett Road, Springfield, Ohio 45505.

358. The Venlafaxine HCL Contract states that, "A contract will be awarded to the responsible offeror that submits an offer meeting the solicitation requirements, and is the lowest price technically acceptable offer."

359. The Venlafaxine HCL Contract provides that the Government may terminate the contract for cause if Defendant AvKARE fails to comply with any contract terms and conditions. In the event of such a termination for cause, Defendant AvKARE shall be liable to the Government for any and all rights and remedies provided by law.

360. The Venlafaxine HCL Contract provides that all delivery orders under that contract "are subject to the terms and conditions of this contract."

361. The Venlafaxine HCL Contract specifically requires Defendant AvKARE to comply with FAR provision 52.225-5, Trade Agreements (FEB 2016) (19 U.S.C. § 2501, *et seq*., 19 U.S.C. § 3301 note).

362. The Venlafaxine HCL Contract also specifically requires Defendant AvKARE to certify that "each end product . . . is a U.S.-made or designated country end product, as defined in the clause of this solicitation entitled 'Trade Agreements'" and to list non-compliant end products. This provision of the Venlafaxine HCL Contract also expressly states that "The Government will consider for award only offers of U.S.-made or designated country end products unless the Contracting Officer determines that there are no offers for such products or that the offers for such products are insufficient to fulfill the requirements of the solicitation."[14]

363. Defendant AvKARE is required to certify Trade Agreements compliance on an

[14] No such determinations were made by the Contracting Officer.

annual basis.

364. On December 17, 2015, February 17, 2016, and February 9, 2017, David Dunston attested to the accuracy of AvKARE's Trade Agreements compliance and made these annual certifications.

365. Specifically, on December 17, 2015, David Dunston attested to the accuracy of AvKARE's certification and executed the Trade Agreements certification for AvKARE for the time period of December 17, 2015 through December 17, 2016, certifying on behalf of AvKARE that each end product (except those listed) is a U.S.-made or designated country end product. (No non-compliant end products were listed).

366. On February 17, 2016, and February 9, 2017, David Dunston executed this same Trade Agreements Certificate for Defendant AvKARE for the respective one year period beginning on each of those dates.

367. By submission of its offer for the Venlafaxine HCL Contract, AvKARE verified that its Trade Agreements certification was current, accurate, complete, and applicable to this solicitation, and incorporated by reference.

368. However, the venlafaxine HCL tablets Defendant AvKARE provides to governmental entities under Contract No. VA797P-16-C-0060 are not U.S.-made or designated country end products as defined in FAR provision 52.225-5, Trade Agreements (FEB 2016).

369. The venlafaxine HCL tablets supplied by Defendant AvKARE under the Venlafaxine HCL Contract are end products of a non-TAA designated country of origin.

370. In order to obtain the Venlafaxine HCL Contract, additional option years under that contract, and payments pursuant to that contract, Defendant AvKARE falsely certified that

the venlafaxine HCL it was selling was a "U.S.-made or designated country end product."

371. Because the venlafaxine HCL tablets distributed by Defendant AvKARE are not a product of a TAA-designated country of origin, they are ineligible for Government procurement under the express terms of Contract No. VA797P-16-C-0060.

372. Defendant AvKARE falsely represented that the venlafaxine HCL it supplied under Contract No. VA797P-16-C-0060 was a TAA-compliant product.

373. Defendant AvKARE's certifications that the venlafaxine HCL tablets supplied under Contract No. VA797P-16-C-0060 were made in the United States or in a TAA "designated country" were false. AvKARE made these false certifications "knowingly," as that term is defined 31 U.S.C § 3729(b)(1).

374. As specified in the Venlafaxine HCL Contract and reiterated in the Trade Agreements Certificate, the Government would not have awarded the Venlafaxine HCL Contract, or option years under that contract, to Defendant AvKARE and AvKARE would not have been paid any money for venlafaxine HCL tablets if AvKARE had truthfully disclosed in its bid that the country of origin for the venlafaxine HCL tablets was a non-TAA country of origin.

375. All claims for payment for venlafaxine HCL tablets supplied by Defendant AvKARE under Contract No. VA797P-16-C-0060 are false claims.

K. The Montelukast SOD Contract: VA Contract No. VA797P-16-C-0068

376. On April 15, 2016, the VA issued Solicitation No. VA797P-16-R-0055 seeking offers to supply its requirements of montelukast SOD tablets.

377. Montelukast SOD is a generic version of the brand name drug Singulair. It is used to ease allergy signs, to prevent exercise-induced breathing problems, and to treat or prevent

asthma.

378. By making an offer on Solicitation No. VA797P-16-R-0055, Defendant AvKARE agreed to furnish and deliver montelukast SOD tablets subject to the terms and conditions specified in the solicitation.

379. On July 15, 2016, Defendant AvKARE was awarded Contract No. VA797P-16-C-0068 to supply montelukast SOD tablets to the VA pursuant to Solicitation No. VA797P-16-R-0055 (collectively the "**Montelukast SOD Contract**").

380. The Montelukast SOD Contract is a firm fixed price requirements contract whereby Defendant AvKARE agreed to supply montelukast SOD tablets for distribution to VA, DoD, IHS, and BoP facilities, as well as to Federal Health Care Centers and to specified State Veteran Homes.

381. The Montelukast SOD Contract is for one base year, with four one-year option years.

382. The Montelukast SOD Contract has a contract award amount of $3,977,231.85. This award amount is an estimate of the total value of all annual orders by the various Government facilities for this drug.

383. The effective date of the base year of the Montelukast SOD Contract was August 9, 2016.

384. On June 27, 2017, the VA exercised the first one year option available under the Montelukast SOD Contract, permitting governmental entities to place orders under that contract from August 9, 2017 through August 8, 2018.

385. The products awarded under the Montelukast SOD Contract are ordered and

distributed through the PPV Program.

386. The Montelukast SOD Contract specifies that PPVs will accept Government orders of montelukast SOD and payment for such orders on behalf of Defendant AvKARE.

387. The Montelukast SOD Contract identifies one VA PPV and five DoD PPVs. Cardinal Health of Dublin, Ohio is one of the designated DoD PPVs.

388. The governmental facilities served under the Montelukast SOD Contract include the VA Medical Center located at 3200 Vine Street, Cincinnati, Ohio 45220; the VA Medical Center Dayton located at 4100 West Third Street, Dayton, Ohio 45428; the VA Medical Center located at 4337 Union Road, Middletown, Ohio 45005, and the VA Outpatient Clinic located at 512 South Burnett Road, Springfield, Ohio 45505.

389. The Montelukast SOD Contract states that, "The Government will make one award for each individual product group or a combination of product groups to the responsible offeror that submits an offer meeting the solicitation requirements, and is the lowest price technically acceptable offer."

390. The Montelukast SOD Contract provides that the Government may terminate the contract for cause if Defendant AvKARE fails to comply with any contract terms and conditions. In the event of such a termination for cause, Defendant AvKARE shall be liable to the Government for any and all rights and remedies provided by law.

391. The Montelukast SOD Contract provides that all delivery orders under that contract "are subject to the terms and conditions of this contract."

392. The Montelukast SOD Contract specifically requires Defendant AvKARE to comply with FAR provision 52.225-5, Trade Agreements (FEB 2016) (19 U.S.C. § 2501, *et seq*.,

19 U.S.C. § 3301 note).

393. The Montelukast SOD Contract also specifically requires Defendant AvKARE to certify that "each end product . . . is a U.S.-made or designated country end product, as defined in the clause of this solicitation entitled 'Trade Agreements'" and to list non-compliant end products. This provision of the Montelukast SOD Contract also expressly states that "The Government will consider for award only offers of U.S.-made or designated country end products unless the Contracting Officer determines that there are no offers for such products or that the offers for such products are insufficient to fulfill the requirements of the solicitation."[15]

394. Defendant AvKARE is required to certify Trade Agreements compliance on an annual basis.

395. On December 17, 2015, February 17, 2016, and February 9, 2017, David Dunston attested to the accuracy of AvKARE's Trade Agreements compliance and made these annual certifications.

396. Specifically, on December 17, 2015, David Dunston attested to the accuracy of AvKARE's certification and executed the Trade Agreements certification for AvKARE for the time period of December 17, 2015 through December 17, 2016, certifying on behalf of AvKARE that each end product (except those listed) is a U.S.-made or designated country end product. (No non-compliant end products were listed).

397. On February 17, 2016, and February 9, 2017, David Dunston executed this same Trade Agreements Certificate for Defendant AvKARE for the respective one year period

[15] No such determinations were made by the Contracting Officer.

beginning on each of those dates.

398. By submission of its offer for the Montelukast SOD Contract, AvKARE verified that its Trade Agreements certification was current, accurate, complete, and applicable to this solicitation, and incorporated by reference.

399. However, the montelukast SOD tablets Defendant AvKARE provides to governmental entities under Contract No. VA797P-16-C-0068 are not U.S.-made or designated country end products as defined in FAR provision 52.225-5, Trade Agreements (FEB 2016).

400. The montelukast SOD tablets supplied by Defendant AvKARE under the Montelukast SOD Contract are end products of a non-TAA designated country of origin.

401. In order to obtain the Montelukast SOD Contract, additional option years under that contract, and payments pursuant to that contract, Defendant AvKARE falsely certified that the montelukast SOD it was selling was a "U.S.-made or designated country end product."

402. Because the montelukast SOD tablets distributed by Defendant AvKARE are not a product of a TAA-designated country of origin, they are ineligible for Government procurement under the express terms of Contract No. VA797P-16-C-0068.

403. Defendant AvKARE falsely represented that the montelukast SOD it supplied under Contract No. VA797P-16-C-0068 was a TAA-compliant product.

404. Defendant AvKARE's certifications that the montelukast SOD tablets supplied under Contract No. VA797P-16-C-0068 were made in the United States or in a TAA "designated country" were false. AvKARE made these false certifications "knowingly," as that term is defined 31 U.S.C § 3729(b)(1).

405. As specified in the Montelukast SOD Contract and reiterated in the Trade

Agreements Certificate, the Government would not have awarded the Montelukast SOD Contract, or option years under that contract, to AvKARE and AvKARE would not have been paid any money for montelukast SOD tablets if AvKARE had truthfully disclosed in its bid that the country of origin for the montelukast SOD tablets was a non-TAA country of origin.

406. All claims for payment for montelukast SOD tablets supplied by Defendant AvKARE under Contract No. VA797P-16-C-0068 are false claims.

L. The Diltiazem Contract: VA Contract No. VA797P-16-C-0074

407. On April 5, 2016, the VA issued Solicitation No. VA797P-16-R-0047 seeking offers to supply its requirements of diltiazem capsules.

408. Diltiazem is a generic version of the brand name drug Cardizem. It is a calcium channel blocker used to treat hypertension (high blood pressure), angina (chest pain), and certain heart rhythm disorders.

409. By making an offer on Solicitation No. VA797P-16-R-0047, Defendant AvKARE agreed to furnish and deliver diltiazem capsules subject to the terms and conditions specified in the solicitation.

410. On August 12, 2016, Defendant AvKARE was awarded Contract No. VA797P-16-C-0074 to supply diltiazem capsules to the VA pursuant to Solicitation No. VA797P-16-R-0047 (collectively the "**Diltiazem Contract**").

411. The Diltiazem Contract is a firm fixed price requirements contract whereby Defendant AvKARE agreed to supply diltiazem capsules for distribution to VA, DoD, IHS, and BoP facilities, as well as to Federal Health Care Centers and to specified State Veteran Homes.

412. The Diltiazem Contract is for one base year, with four one-year option years.

413. The Diltiazem Contract has a contract award amount of $8,386,618.95. This award amount is an estimate of the total value of all annual orders by the various Government facilities for this drug.

414. The effective date of the base year of the Diltiazem Contract was October 7, 2016.

415. On September 22, 2017, the VA exercised the first one year option available under the Diltiazem Contract, permitting governmental entities to place orders under that contract from October 7, 2017 through October 6, 2018.

416. The products awarded under the Diltiazem Contract are ordered and distributed through the PPV Program.

417. The Diltiazem Contract specifies that PPVs will accept Government orders of diltiazem and payment for such orders on behalf of Defendant AvKARE.

418. The Diltiazem Contract identifies one VA PPV and five DoD PPVs. Cardinal Health of Dublin, Ohio is one of the designated DoD PPVs.

419. The governmental facilities served under the Diltiazem Contract include the VA Medical Center located at 3200 Vine Street, Cincinnati, Ohio 45220; the VA Medical Center Dayton located at 4100 West Third Street, Dayton, Ohio 45428; the VA Medical Center located at 4337 Union Road, Middletown, Ohio 45005, and the VA Outpatient Clinic located at 512 South Burnett Road, Springfield, Ohio 45505.

420. The Diltiazem Contract states that, "A contract will be awarded to the responsible offeror that submits an offer meeting the solicitation requirements, and is the lowest price technically acceptable offer."

421. The Diltiazem Contract provides that the Government may terminate the contract

for cause if Defendant AvKARE fails to comply with any contract terms and conditions. In the event of such a termination for cause, Defendant AvKARE shall be liable to the Government for any and all rights and remedies provided by law.

422. The Diltiazem Contract provides that all delivery orders under that contract "are subject to the terms and conditions of this contract."

423. The Diltiazem Contract specifically requires Defendant AvKARE to comply with FAR provision 52.225-5, Trade Agreements (FEB 2016) (19 U.S.C. § 2501, *et seq*., 19 U.S.C. § 3301 note).

424. The Diltiazem Contract also specifically requires Defendant AvKARE to certify that "each end product . . . is a U.S.-made or designated country end product, as defined in the clause of this solicitation entitled 'Trade Agreements'" and to list non-compliant end products. This provision of the Diltiazem Contract also expressly states that "The Government will consider for award only offers of U.S.-made or designated country end products unless the Contracting Officer determines that there are no offers for such products or that the offers for such products are insufficient to fulfill the requirements of the solicitation."[16]

425. Defendant AvKARE is required to certify Trade Agreements compliance on an annual basis.

426. On December 17, 2015, February 17, 2016, and February 9, 2017, David Dunston attested to the accuracy of AvKARE's Trade Agreements compliance and made these annual certifications.

[16] No such determinations were made by the Contracting Officer.

427. Specifically, on December 17, 2015, David Dunston attested to the accuracy of AvKARE's certification and executed the Trade Agreements certification for AvKARE for the time period of December 17, 2015 through December 17, 2016, certifying on behalf of AvKARE that each end product (except those listed) is a U.S.-made or designated country end product. (No non-compliant end products were listed).

428. On February 17, 2016, and February 9, 2017, David Dunston executed this same Trade Agreements Certificate for Defendant AvKARE for the respective one year period beginning on each of those dates.

429. By submission of its offer for the Diltiazem Contract, AvKARE verified that its Trade Agreements certification was current, accurate, complete, and applicable to this solicitation, and incorporated by reference.

430. However, the diltiazem capsules Defendant AvKARE provides to governmental entities under Contract No. VA797P-16-C-0074 are not U.S.-made or designated country end products as defined in FAR provision 52.225-5, Trade Agreements (FEB 2016).

431. The diltiazem capsules supplied by Defendant AvKARE under the Diltiazem Contract are end products of a non-TAA designated country of origin.

432. In order to obtain the Diltiazem Contract, additional option years under that contract, and payments pursuant to that contract, Defendant AvKARE falsely certified that the diltiazem it was selling was a "U.S.-made or designated country end product."

433. Because the diltiazem capsules distributed by Defendant AvKARE are not a product of a TAA-designated country of origin, they are ineligible for Government procurement under the express terms of Contract No. VA797P-16-C-0074.

434. Defendant AvKARE falsely represented that the diltiazem it supplied under Contract No. VA797P-16-C-0074 was a TAA-compliant product.

435. Defendant AvKARE's certifications that the diltiazem capsules supplied under Contract No. VA797P-16-C-0074 were made in the United States or in a TAA "designated country" were false. AvKARE made these false certifications "knowingly," as that term is defined 31 U.S.C § 3729(b)(1).

436. As specified in the Diltiazem Contract and reiterated in the Trade Agreements Certificate, the Government would not have awarded the Diltiazem Contract, or option years under that contract, to AvKARE and AvKARE would not have been paid any money for diltiazem capsules if AvKARE had truthfully disclosed in its bid that the country of origin for the diltiazem capsules was a non-TAA country of origin.

437. All claims for payment for diltiazem capsules supplied by Defendant AvKARE under Contract No. VA797P-16-C-0074 are false claims.

M. The Benazepril HCL Contract: VA Contract No. VA797P-16-C-0077

438. On July 22, 2016, the VA issued Solicitation No. VA797P-16-R-0083 seeking offers to supply its requirements of benazepril HCL tablets.

439. Benazepril HCL is a generic version of the brand name drug Lotensin. It is an ACE (angiotensin converting enzyme) inhibitor used to treat hypertension (high blood pressure).

440. By making an offer on Solicitation No. VA797P-16-R-0083, Defendant AvKARE agreed to furnish and deliver benazepril HCL tablets subject to the terms and conditions specified in the solicitation.

441. On September 7, 2016, Defendant AvKARE was awarded Contract No. VA797P-

16-C-0077 to supply benazepril HCL tablets to the VA pursuant to Solicitation No. VA797P-16-R-0083 (collectively the "**Benazepril HCL Contract**").

442. The Benazepril HCL Contract is a firm fixed price requirements contract whereby Defendant AvKARE agreed to supply benazepril HCL tablets for distribution to VA, DoD, IHS, and BoP facilities, as well as to Federal Health Care Centers and to specified State Veteran Homes.

443. The Benazepril HCL Contract is for one base year, with four one-year option years.

444. The Benazepril HCL Contract has a contract award amount of $4,110,198.75. This award amount is an estimate of the total value of all annual orders by the various Government facilities for this drug.

445. The effective date of the base year of the Benazepril HCL Contract was November 6, 2016.

446. On September 21, 2017, the VA exercised the first one year option available under the Benazepril HCL Contract, permitting governmental entities to place orders under that contract from November 6, 2017 through November 5, 2018.

447. The products awarded under the Benazepril HCL Contract are ordered and distributed through the PPV Program.

448. The Benazepril HCL Contract specifies that PPVs will accept Government orders of benazepril HCL and payment for such orders on behalf of Defendant AvKARE.

449. The Benazepril HCL Contract identifies one VA PPV and five DoD PPVs. Cardinal Health of Dublin, Ohio is one of the designated DoD PPVs.

450. The governmental facilities served under the Benazepril HCL Contract include the VA Medical Center located at 3200 Vine Street, Cincinnati, Ohio 45220; the VA Medical Center Dayton located at 4100 West Third Street, Dayton, Ohio 45428; the VA Medical Center located at 4337 Union Road, Middletown, Ohio 45005, and the VA Outpatient Clinic located at 512 South Burnett Road, Springfield, Ohio 45505.

451. The Benazepril HCL Contract states that, "A contract will be awarded to the responsible offeror that submits an offer meeting the solicitation requirements, and is the lowest price technically acceptable offer."

452. The Benazepril HCL Contract provides that the Government may terminate the contract for cause if Defendant AvKARE fails to comply with any contract terms and conditions. In the event of such a termination for cause, Defendant AvKARE shall be liable to the Government for any and all rights and remedies provided by law.

453. The Benazepril HCL Contract provides that all delivery orders under that contract "are subject to the terms and conditions of this contract."

454. The Benazepril HCL Contract specifically requires Defendant AvKARE to comply with FAR provision 52.225-5, Trade Agreements (FEB 2016) (19 U.S.C. § 2501, *et seq*., 19 U.S.C. § 3301 note).

455. The Benazepril HCL Contract also specifically requires Defendant AvKARE to certify that "each end product . . . is a U.S.-made or designated country end product, as defined in the clause of this solicitation entitled 'Trade Agreements'" and to list non-compliant end products. This provision of the Benazepril HCL Contract also expressly states that "The Government will consider for award only offers of U.S.-made or designated country end products

unless the Contracting Officer determines that there are no offers for such products or that the offers for such products are insufficient to fulfill the requirements of the solicitation."[17]

456. Defendant AvKARE is required to certify Trade Agreements compliance on an annual basis.

457. On December 17, 2015, February 17, 2016, and February 9, 2017, David Dunston attested to the accuracy of AvKARE's Trade Agreements compliance and made these annual certifications.

458. Specifically, on December 17, 2015, David Dunston attested to the accuracy of AvKARE's certification and executed the Trade Agreements certification for AvKARE for the time period of December 17, 2015 through December 17, 2016, certifying on behalf of AvKARE that each end product (except those listed) is a U.S.-made or designated country end product. (No non-compliant end products were listed).

459. On February 17, 2016, and February 9, 2017, David Dunston executed this same Trade Agreements Certificate for Defendant AvKARE for the respective one year period beginning on each of those dates.

460. By submission of its offer for the Benazepril HCL Contract, AvKARE verified that its Trade Agreements certification was current, accurate, complete, and applicable to this solicitation, and incorporated by reference.

461. However, the benazepril HCL tablets Defendant AvKARE provides to governmental entities under Contract No. VA797P-16-C-0077 are not U.S.-made or designated

[17] No such determinations were made by the Contracting Officer.

country end products as defined in FAR provision 52.225-5, Trade Agreements (FEB 2016).

462. The benazepril HCL tablets supplied by Defendant AvKARE under the Benazepril HCL Contract are end products of a non-TAA designated country of origin.

463. In order to obtain the Benazepril HCL Contract, additional option years under that contract, and payments pursuant to that contract, Defendant AvKARE falsely certified that the benazepril HCL it was selling was a "U.S.-made or designated country end product."

464. Because the benazepril HCL tablets distributed by Defendant AvKARE are not a product of a TAA-designated country of origin, they are ineligible for Government procurement under the express terms of Contract No. VA797P-16-C-0077.

465. Defendant AvKARE falsely represented that the benazepril HCL it supplied under Contract No. VA797P-16-C-0077 was a TAA-compliant product.

466. Defendant AvKARE's certifications that the benazepril HCL tablets supplied under Contract No. VA797P-16-C-0077 were made in the United States or in a TAA "designated country" were false. AvKARE made these false certifications "knowingly," as that term is defined 31 U.S.C § 3729(b)(1).

467. As specified in the Benazepril HCL Contract and reiterated in the Trade Agreements Certificate, the Government would not have awarded the Benazepril HCL Contract, or option years under that contract, to Defendant AvKARE and AvKARE would not have been paid any money for benazepril HCL tablets if AvKARE had truthfully disclosed in its bid that the country of origin for the benazepril HCL tablets was a non-TAA country of origin.

468. All claims for payment for benazepril HCL tablets supplied by Defendant AvKARE under Contract No. VA797P-16-C-0077 are false claims.

COUNT I-VIOLATION OF 31 U.S.C. § 3729(A)(1)(A)

469. Relators incorporate by reference and re-allege the preceding paragraphs as if fully restated.

470. Defendant AvKARE, by and through its officers, members, agents, and employees, authorized the actions related to the conduct alleged above.

471. By virtue of the conduct described above, Defendant AvKARE knowingly presented or caused to be presented false or fraudulent claims for payment in violation of 31 U.S.C. § 3729(a)(1)(A).

472. Defendant AvKARE "knowingly" violated the False Claims Act, as that term is defined in 31 U.S.C. § 3729(b)(1). As to each of the above allegations, Defendant AvKARE acted with actual knowledge of the information, in deliberate ignorance of the truth or falsity of the information, and/or in reckless disregard of the truth or falsity of the information.

473. As a result of Defendant AvKARE's violations of 31 U.S.C. § 3729(a)(1)(A), the Government has suffered actual damages in an amount to be determined at trial.

COUNT II-VIOLATION OF 31 U.S.C. § 3729(A)(1)(B)

474. Relators incorporate by reference and re-allege the preceding paragraphs as if fully restated.

475. Defendant AvKARE, by and through its officers, members, agents, and employees, authorized the actions related to the conduct alleged above.

476. By virtue of the conduct described above, Defendant AvKARE knowingly made, used or caused to be made or used, false records or statements material to false or fraudulent claims in violation of 31 U.S.C. § 3729(a)(1)(B).

477. Defendant AvKARE "knowingly" violated the False Claims Act, as that term is defined in 31 U.S.C. § 3729(b)(1). As to each of the above allegations, Defendant AvKARE acted with actual knowledge of the information, in deliberate ignorance of the truth or falsity of the information, and/or in reckless disregard of the truth or falsity of the information.

478. As a result of Defendant AvKARE's violations of 31 U.S.C. § 3729(a)(1)(B), the Government has suffered actual damages in an amount to be determined at trial.

PRAYER FOR RELIEF

WHEREFORE Relators, on behalf of themselves and the United States, pray for judgment against Defendant AvKARE as follows:

A. That this Court enter judgment against Defendant AvKARE in an amount equal to three times the amount of damages sustained by the United States because of Defendant AvKARE's acts in violation of the False Claims Act, plus the maximum civil penalty for each violation of the False Claims Act, as provided by 31 U.S.C. § 3729(a)(1);

B. That Relators be awarded all reasonable expenses incurred, plus reasonable attorneys' fees and costs, in accord with 31 U.S.C. § 3730(d);

C. That, in the event the United States intervenes, that Relators be awarded 25% of the proceeds of the action or of any settlement, in accord with 31 U.S.C. § 3730(d)(1);

D. That, in the event the United States does not intervene, that Relators be awarded 30% of the proceeds of the action or of any settlement, in accord with 31 U.S.C. § 3730(d)(2);

E. That Relators be awarded a share of any alternate remedy that the United States elects to pursue;

F. That Defendant AvKARE, its subsidiaries, affiliates, and related organizations be

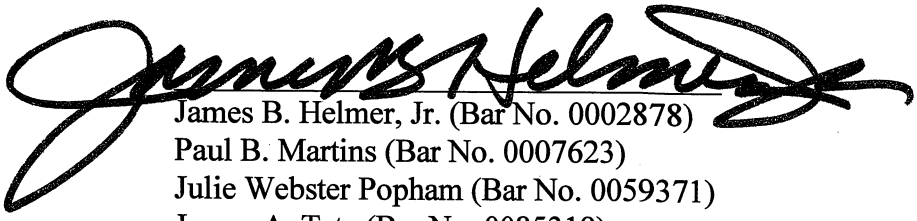
found to have violated the False Claims Act and be enjoined from future violations of that act;

G. That the United States and Relators be awarded pre-judgment and post-judgment interest; and

H. That the United States and Relators receive all relief, both at law and in equity to which they may be reasonably entitled.

Respectfully submitted,

Date: December 1, 2017



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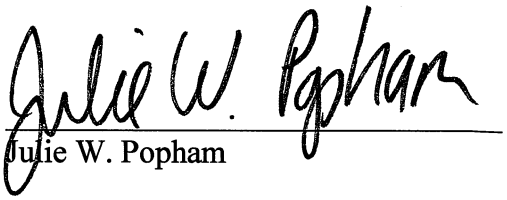
CERTIFICATE OF SERVICE

I hereby certify that on December 1, 2017, I served the foregoing:

Via Federal Express and Certified U.S. Mail upon:
Hon. Jefferson B. Sessions
Attorney General of the United States
United States Department of Justice
950 Pennsylvania Avenue N.W.
Washington, D.C. 20530

And Via Hand Delivery upon:
Hon. Benjamin C. Glassman
United States Attorney
Hon. William B. King II
Assistant United States Attorney
221 E. Fourth Street, Suite 400
Cincinnati, OH 45202



Julie W. Popham